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**FINAL SUBMISSION OF  
THE CANADIAN RED CROSS SOCIETY**

**TO THE  
COMMISSION OF INQUIRY ON THE  
BLOOD SYSTEM IN CANADA**

**December 6, 1996**

**Volume 4 of 4**



The Canadian Red Cross Society



# THE CANADIAN RED CROSS SOCIETY

## FINAL SUBMISSIONS

### FUTURE OF THE CANADIAN BLOOD SYSTEM

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**Final Submissions: Future of the Canadian Blood System**

# **Organizational, Operational & Funding Structure**

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## **1. Introduction**

The historical section of the Red Cross submission begins with an overview of the Blood System that was in place prior to the tragedy of AIDS infection in the blood supply. That descriptive overview is followed by a more detailed review of the Red Cross's relationship with governments. The facts specific to AIDS and hepatitis in the blood supply are then set out in detail, to illustrate the actual operation and effect of that structure in practice. With that foundation, the Commissioner will be in a position to assess what elements of the system structure and operation were at play during Canada's response to the AIDS crisis.

As a parallel process, the section on the future begins with an overview of the Blood System of today, highlighting significant changes and differences from the system described in the historical section. Real-life examples of current issues and difficulties are used to illustrate some areas of ongoing friction which indicate that reform is still needed.

With this solid foundation in the structures and issues of both the past and present, a selection of possible structural models are presented, with a review of their strengths and weaknesses from the current blood supplier's perspective. It is, in our view, the systemic failures that are key to understanding both past tragedies and future improvements in the quality, safety and adequacy of supply of blood and blood products.

“...No useful purpose, it seems to me, can be served by proceeding against scapegoats when the problem lies in the system itself, and the solution in the reform of the system.”<sup>1</sup>

## **2. Current International Environment**

Not least among the considerations that have led to a fundamental shift in the paradigm for blood collection and distribution systems around the world is the realization that they were structurally unprepared to meet the challenge of the AIDS pandemic in the early 1980s. Since the AIDS tragedy affected virtually all blood systems worldwide, each one has been struggling to adapt their systems and structures to be ready for new threats to the blood supply. In the process, certain dominant themes have emerged.

Public confidence in the safety of the blood supply has perhaps never been lower, while in reality the level of safety has never been higher. Current levels of confidence must always be qualified however with the keen awareness that there may well be something out there that we don't yet know about - such as the HIV virus in the early 1980s. The Management Committee, nevertheless, expressed its

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<sup>1</sup> “Report of the Commission of Inquiry into the Confidentiality of Health Information,” as quoted in the Royal Society of Canada report “AIDS - A Perspective for Canadians,” p.10).



concern over this phenomenon in its 1994 Report, noting that the public fear of blood risks is out of proportion to the actual known risks. This phenomenon is in no way unique to Canada, as demonstrated by a recent speech by the chairman of the US Health and Human Services Blood Safety Committee in October 1996.

Blood and blood product recipients ("consumers") are more well-informed about the operation of the blood supply than ever before, and have emerged as a dominant voice in advocating change in Blood System policies and practices. Many other aspects of science and medicine have been growing towards increased consumer involvement in decision-making; the AIDS experience for blood product consumers has accelerated this process tremendously. Blood services in other countries<sup>3</sup> are also struggling to identify an appropriate level of involvement and accountability for consumers in decision-making processes.

In 1992, Dr. David Kessler, Commissioner of the US Food and Drug Administration (USFDA) said, "The nation's blood banks must undergo a change in their culture and practices - they must move from being medical services agencies to drug manufacturers."<sup>4</sup> The worldwide movement of blood service providers towards adoption of current Good Manufacturing Practices and other aspects of a manufacturing culture was acknowledged by the Management Committee. With this momentum, no blood service can ignore the new paradigm without being compared unfavourably to those who are striving to adapt to it.

In addition, the trend towards harmonization of international standards and practices continues. Complementary to the regulatory regime, the International Society for Blood Transfusion sets standards for labelling as well as best practices for transfusion medicine and manufacturing processes. Blood service organizations in various countries are expressing interest in the standards established by the International Organization for Standardization (ISO), even though ISO provides generic standards applicable to any industry--not specific to pharmaceuticals or biologics. In turn, the USFDA seems to be moving towards harmonization of some of its cGMP regulations with ISO standards<sup>5</sup>. The Canadian Red Cross initiated a move towards ISO certification, but decided it

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<sup>2</sup> An account of Dr. Lee's presentation was reported in *America's Blood Centers Newsletter*, October 18, 1996, attached as Appendix A. See also the evidence of Dr. Tom Zuck, pp. 22299-22300.

<sup>3</sup> In a 1996 *Transfusion* article "Whither the Blood Products Advisory Committee?" M. H. Sayers describes the overhaul of the USFDA Blood Products Advisory Committee in 1995 to entrench consumer representation, attached as Appendix B.

<sup>4</sup> From his remarks to the House Energy and Commerce Committee's Sub-committee on Oversight and Investigations, July 28, 1993; quoted in *Council of Community Blood Centers (CCBC) Newsletter*, July 30, 1993.

<sup>5</sup> See "FDA Issues Proposed Amendments to Drug GMPs: Seeks Harmonization of Quality Standards with ISO 9000," in *CCBC Newsletter*, May 10, 1996, attached as Appendix C.



could not simultaneously manage ISO certification and the implementation of cGMPs. It does intend to revisit the issue of ISO certification once the cGMP implementation has been achieved.

While there is fear on the part of the users of the blood supply, other fears have come into play as well. It must be acknowledged that fear of liability for transfusion-associated infections can have a significant impact on the actions of all those involved in the Blood System. Most notably, the recent New Jersey Supreme Court case *Snyder vs. American Association of Blood Banks et al.* held that the American Association of Blood Banks (AABB)--a voluntary, not-for-profit professional association--was negligent in having failed to set a certain standard in the early 1980s. This ruling sent shock waves through the American blood collection community, causing the AABB to seriously consider limiting its standard-setting activities.<sup>6</sup>

### 3. Current Canadian Environment

The Blood System in Canada is an anomaly in many respects. It is the only operational national health program in a federal state where the federal government sets the standards for health and the provinces deliver health services within the framework of these standards. The federal government cannot make decisions about delivery. These must be made either conjointly or by the provinces alone.

The Blood System's national character, including national pricing, interprovincial transfers, national standards and national regulation, is well worth safeguarding. Australia has recently moved from a state-based blood system to a national one. In healthcare and many other areas, our Federal Government is divesting itself of decision making duties, either to lower levels of government or to the private sector. In the Blood System, on the contrary, it has taken a leadership and coordinating role in the Federal/Provincial/Territorial Initiative. Can the benefits of a national blood program be maintained in the current environment?

The Blood System, as a national program, would benefit from continuing and increasing involvement by the Federal Government in policy making that would provide appropriate blood services at a similar level for the country as a whole. It also has a role to play in giving the partners a fair, equitable and practical Blood System within which to operate.

The public environment in which the blood system must operate has become very highly charged emotionally. With good reason, the stories of those infected

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<sup>6</sup> The options it considered are set out in an article, "AABB Board to Consider Change to Standard-Setting Activities," *American Association of Blood Banks (AABB) News Briefs*, September 1996. The AABB Board decision is set out in the attached statement entitled "AABB Board Reaffirms Standard Setting Role," issued by the AABB in October 1996. Both items are attached as Appendix D.



receive extensive media coverage. The stories are not only medical, but also financial. Infected individuals not only suffer from serious illness, but must also continually engage in major public campaigns to achieve the financial support for their medical costs, or to maintain a decent standard of living. It must be noted, that where governments have moved expeditiously to deal creatively with the issue of financial assistance for those infected, the atmosphere of crisis surrounding the blood system as a whole has been greatly reduced. Often ignored in this public controversy, is the simple reality that approximately 600,000 Canadians use blood products every year, and that their lives are often saved or significantly improved as the result.

Reducing government expenditure is also one of the key themes of the current Canadian environment. Although the federal government may consider the blood supplier to be a manufacturer of biological products, the provinces see the blood supplier as a part of the health care system. Fundamentally different approaches exist for controlling costs depending on which philosophy is the guiding one. The reality for the Red Cross, has been to undertake a massive and expensive conversion of its operations to meet emerging new world standards based on drug manufacturing concepts adopted by the regulatory authorities, in a system where health care officials control budgetary allocations and where reductions and cutbacks are the order of the day.

The blood system also operates in a public environment that increasingly demands "no risk" - or at least no externally generated risk. Tobacco is not generally seen to have saved many lives. It is in fact estimated that 40,000 Canadians die each year from tobacco related illness. Blood products save tens of thousands of lives each year in Canada, yet the media constantly refer to the 3,000 who may die from the HIV and Hepatitis C infections of the eighties as *Canada's worst ever public health tragedy*. Blood, with its deep linkages to religion, literature, art and love, with its position as one of the pillars of modern medicine, with its supply historically provided in Canada by what is arguably the world's most visible institution, and with the complex interactions of the thirteen federal/provincial/territorial governments that form our federal state, will clearly remain an issue to which the highest of risk standards is applied.

#### 4. Structure of the Current Canadian Blood System

##### Actors within the Blood System

The lack of standardized and agreed terminology frequently confuses discussion on the Canadian Blood System. What is the Canadian Blood System? The Red Cross, following the terminology agreed in its Master Agreement with the provinces, distinguishes between the *national blood supply program*, and the much broader *Canadian Blood System*. Although the categorization is never totally neat and clean, the *national blood supply program* consists basically of the regulator (the Bureau of Biologics and Radiopharmaceuticals of the federal government's Health Canada), the operator (the Canadian Red Cross) and the coordinator/funder (the Canadian Blood Agency). The broader Canadian Blood System could be said to



include also government health ministries, special interest groups, blood donors, private blood product manufacturing firms, hospitals and clinics, physicians, and patients<sup>7</sup>.

While the Blood System in the 1980s functioned with very little in the way of formal structure or delegation, some steps towards defining the parties' respective roles and responsibilities have been taken in the past few years. In April 1995, a Master Agreement among all provinces and territories, the Canadian Blood Agency, and the Canadian Red Cross was signed.<sup>8</sup> The Master Agreement consisted of a set of general principles of responsibility and accountability, which would require further elaboration, either formally through more detailed agreements or through the accumulated refinements arising from its implementation. That agreement assigned, for the first time, specific roles to each of the parties who collectively operated the Blood System. In 1996, to further define the mechanics of the arrangement at the operational level, the Canadian Red Cross signed a Supply Agreement with the Canadian Blood Agency.

## Recruitment

Blood Donor Recruitment continues to be an activity performed by the Canadian Red Cross, although its place in the structure has changed. In 1994, the full integration of blood donor recruitment into blood services was achieved from coast to coast.<sup>9</sup> Historically, blood donor recruitment--because of its deep roots to the volunteer sector of the Red Cross--had been managed by the Divisional offices. For safety reasons, it was necessary to maintain full integration and therefore an uninterrupted line of accountability between donor recruitment and the other related functions such as collecting, testing, processing, and distribution.

In the past, Canadians could count on an abundant supply of blood. More recently, a combination of factors, including a restructured economy, changing lifestyles, the lack of mechanisms to monitor utilization practices or hospital inventory practices, even the impact of the Commission of Inquiry on the Blood System in Canada, has led to chronic tight supply. Major improvements in the methods used to recruit and retain donors will be required to ensure adequacy of supply. This becomes more necessary every day, as donors, along with all types of volunteers, become scarcer in urban areas, and donation time increases as screening becomes more intrusive due to regulatory and safety measures.

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<sup>7</sup> See Figure 1 for a graphic representation of the actors in the current Canadian Blood System.

<sup>8</sup> See the "Response of the Canadian Red Cross to the Interim Report," September 27, 1995, for further discussion on and a copy of the Master Agreement.

<sup>9</sup> See also the "Response of the Canadian Red Cross Society to the Report of the Management Committee," December 16, 1994.



# THE CURRENT CANADIAN BLOOD SYSTEM

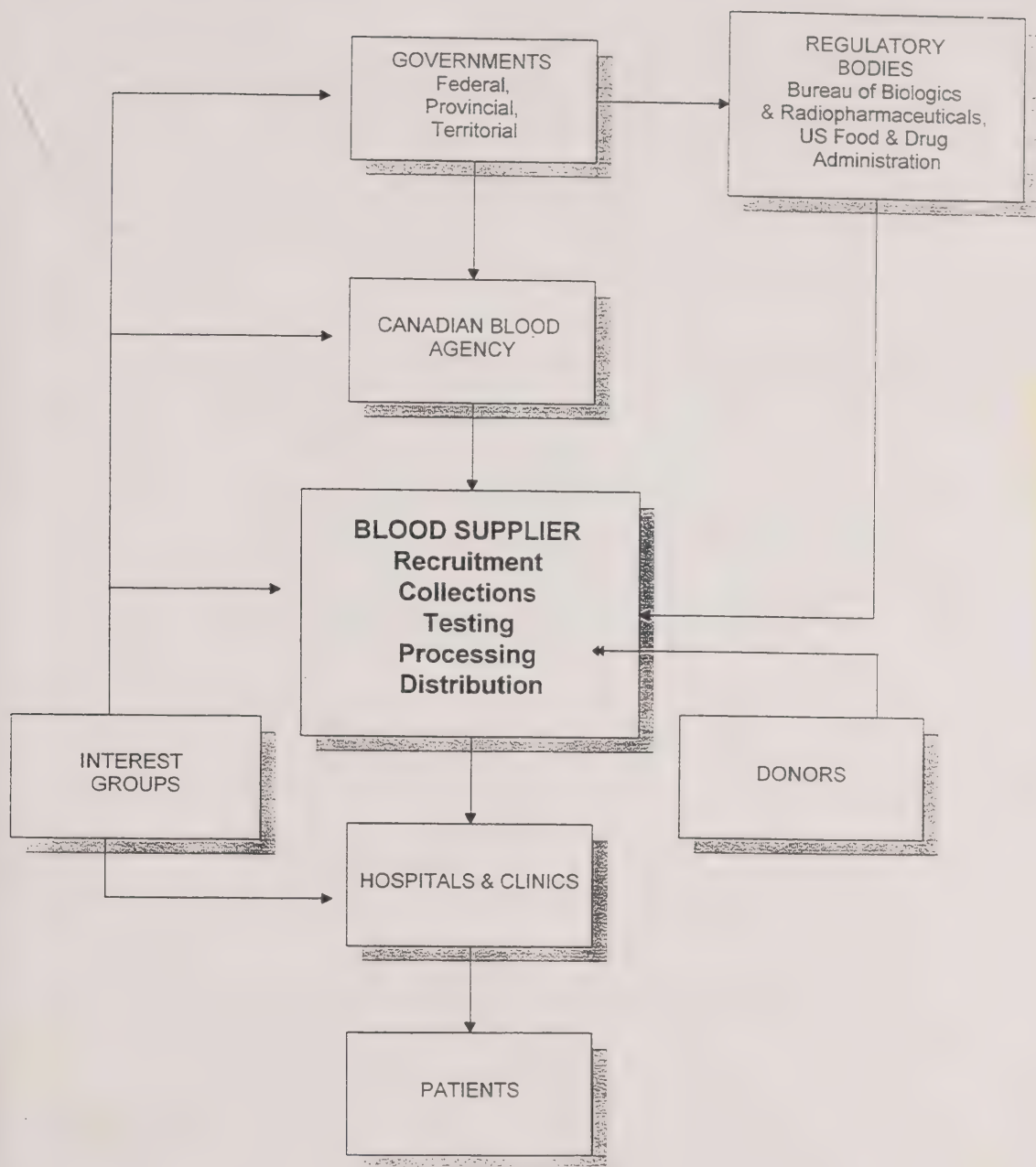


FIGURE 1



In 1996, a new program was initiated to address the need for a true customer-service approach to donor recruitment, donor service, and donor retention. The objective is a base of safe donors who give blood often enough to meet Canada's needs for each type of product. The program, entitled "Donors First," consists of the following elements: identification of donor populations, understanding donor motivation, developing a "donors first" attitude, improving the effectiveness and promotion of clinics, and providing donors with a donation experience that will ensure that they become or remain regular donors. Monthly donor satisfaction surveys will provide feedback and enable the Blood Centre to make timely adjustments to its donor recruitment strategy.

The provinces and territories have recently reaffirmed their commitment to the principle of voluntary blood donation, as noted in Appendix "A" to the Master Agreement. The Quebec Blood Supply System Report has also recommended that *the supplier or suppliers of blood products must also rely solely on volunteer donors*.<sup>10</sup> The Canadian blood supply continues to be maintained through a fully voluntary and non-remunerated blood donor system, though until plasma self-sufficiency is attained it must continue to rely on commercial fractionated products made from paid donors' plasma. In contrast, the competitive environment in the United States has motivated blood collection agencies to push the boundaries of "voluntariness" by sweetening donor incentives. The possibility that such donor incentives can risk the safety of the blood supply are now a source of concern in the United States<sup>11</sup>.

Blood donors need an environment that encourages candour and commitment, but which discourages inappropriate donors from donating. These competing public interests are reviewed and a legislative scheme proposed in the accompanying analysis entitled "Protection of Blood Donor Confidentiality."

#### Whole Blood Collection & Processing

Blood collection operations continue to be performed by the Canadian Red Cross within a network of 17 Blood Centres across the country. Management structures have been modified both within the Blood Centres and within the national organization<sup>12</sup>.

Some functions previously carried out by each Blood Centre are now being organized on a regional basis, both to improve cost-effectiveness and cost-efficiency, and to make it easier to implement, monitor, and modify standardized

<sup>10</sup> "The Québec Blood Supply System," Report of the Québec Committee on the Supply, Management and Distribution of Blood, November 1996.

<sup>11</sup> See "Special Report: Donor Incentives Discussed at FDA Workshop," CCBC Newsletter, September 27, 1996, attached as Appendix E.

<sup>12</sup> The rationale for the restructuring and a description of the changes were provided in the "Response of The Canadian Red Cross Society to the Interim Report," September 27, 1995.



manufacturing practices. To this end, in 1996 the laboratory testing and administrative functions of Quebec City Blood Centre were moved to the Montreal Blood Centre.

Another significant change in the management structure of each Blood Centre was implemented in 1995. Now, each Blood Centre is under the management control of a Centre Director, a full-time manager who may or may not be a physician. Medical issues are managed by Medical Officers at each Blood Centre. The Medical Officer is an important member of the management team and is expected to provide scientific and medical input and advice on changes in the technical and clinical aspects of blood collection, testing and processing, and transfusion medicine to his/her colleagues in the medical community, through the Regional Medical Officer to the Associate National Director, Medical and Scientific Affairs, as well as--routinely-- to the centre management team.

In this way, medical and manufacturing issues are linked but separate, with qualified managers in charge of management, with a much more effective use of physicians' time and expertise. Each Blood Centre now reports to one of three Regional General Managers (Western, Central, and Eastern), who in turn are responsible to the National Director, Blood Services for the operation of all Blood Centres within their Region.

Implementation of current Good Manufacturing Practices and the Regulatory Compliance Project continue as quickly as funding and regulatory approval permit.<sup>13</sup>

The need for an integrated computer system to support blood operations was acknowledged by the Management Committee and was reflected in the Interim Report.<sup>14</sup> Implementation of the custom-developed Computerized Information System for Centre Operations (CISCO) is proceeding. At present, software development and testing have been completed; SOPs are being adapted to the system; and training materials are under development. Field evaluation is underway in Edmonton Blood Centre.

#### **Plasma Collection and Processing**

For many years, Canadian plasma was sent to an American fractionation facility for processing, given the absence of a suitable domestic fractionation facility. Canadian plasma included both plasma collected by apheresis (source plasma), as well as the plasma component of whole blood donations (recovered plasma). In mid-1994, due to a change in United States Food and Drug Administration

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<sup>13</sup> See the "Response of The Canadian Red Cross Society to the Interim Report." September 27, 1995, for further background information.

<sup>14</sup> See the "Response of the Canadian Red Cross Society to the Report of the Management Committee," December 16, 1994, and the "Response of The Canadian Red Cross Society to the Interim Report," September 27, 1995, for further background information.



(USFDA) regulatory policy, shipment of Canadian source plasma was prohibited from entering the United States, even though it was all destined to be returned to the Canadian market. The USFDA allowed continued shipment of Canadian recovered plasma to the US fractionator on the understanding that the Canadian Red Cross would actively pursue USFDA licensure.

Since source plasma could no longer be shipped to the US for fractionation, Canadian plasmapheresis collections were scaled back, an action which might have resulted in a significant setback in the drive towards self-sufficiency in Canadian plasma products. To counteract this potential effect, steps have been taken to maintain the maximum possible Canadian content in the plasma-derived products used by Canadians. At present, five Blood Centres continue plasmapheresis operations only to the extent required to supply hospitals with their fresh plasma needs. This freed up much of the recovered plasma to be shipped for fractionation. The Canadian Red Cross is meeting approximately 70% of the pre-1994 level of annual plasma shipments.

In addition to the whole blood collection centres, the Red Cross opened its first ever plasma collection centre, in Thunder Bay, Ontario in 1996, and is well on its way to recruiting its target of 4-5,000 plasma donors from a population base of 100,000. Since this centre has been designed from the outset to meet USFDA requirements, an application for license will be made before applications will be made for the other blood centres. This should permit, in the near future, source plasma to be shipped to the United States for fractionation.

The Thunder Bay centre will spearhead the drive towards total self-sufficiency in Canadian plasma, to be achieved by establishing five to seven plasma centres in total by the year 2000. These centres will each collect approximately 30,000 litres of plasma per year, which, when combined with plasmapheresis operations in blood centres and recovered plasma, should meet the national demand of 400,000 litres. The second Centre will be established in Prince Edward Island, to become operational in 1997.

The other aspect of self-sufficiency is domestic fractionation capability. The Canadian Red Cross Fractionation Corporation<sup>15</sup> is proceeding with its plans to establish its plant in Bedford, Nova Scotia in cooperation with Bayer Corporation, a proven leader in the field of plasma fractionation worldwide.

## Distribution

The Red Cross continues to be, in effect, the sole licensed distributor of blood components and the largest licensed distributor of fractionated blood products in Canada.

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<sup>15</sup> Detailed information on the governance structure of the Corporation as well as its contractual relationship with Bayer Corporation was provided in evidence on December 11 and 12, 1995, and is summarized in Appendix F.



Blood components continue to be delivered to all Canadian hospitals without charge, on a demand basis. According to the Master Agreement, the Canadian Blood Agency is to determine the type and volume of blood to be acquired, which the Society is to use its best efforts to supply.

Red Cross continues to distribute fractionation products. The CBA has recently, through its interpretation of the Master Agreement, assumed the function of purchasing fractionated products by a competitive bidding process. To date, no written contract exists for the distribution by the Red Cross of products purchased in this manner. The Master Agreement provides that, once the fractionation plant is operational, the Red Cross will be the preferred supplier of fractionated products, provided that its products meet required standards of safety and cost.

#### Clinical Usage

Although the Red Cross medical and technical staff provide consultative services to physicians and hospital staff regarding appropriate usage of blood and blood products, the treating physician remains the decision-maker about the appropriate therapy for the patient. Provided that it is a product licensed for distribution in Canada and approved by the Canadian Blood Agency, the Red Cross supplies the desired product on demand.

The Canadian Blood Agency is responsible to collect and analyze data on blood usage for the information of the provinces and territories, pursuant to the Master Agreement.

#### Policy

The seven guiding ministerial principles established in 1989 were reaffirmed by their inclusion in the Master Agreement, though it should be noted that the explanatory commentary beneath each principle had been modified. The Master Agreement further provided for the Canadian Blood Agency to set policies in accordance with the ministerial principles, through a process of stakeholder consultation. Within the framework of these policies, the Red Cross is to establish its own operational policies. These would include internal policies on such issues as donor age criteria, cGMPs, finances, human resources issues, and other corporate policies that affect all parts of the Red Cross.

#### Regulation

The federal government, through Health Canada and its BBR, is the regulator of the blood program in Canada. For reasons mentioned earlier, the USFDA has also assumed an important indirect role in regulating Canadian Red Cross activities as the result of Canada's dependence on a facility located in the United States to fractionate Canadian plasma. In addition to the practical plasma related rationale, the Red Cross has also pursued USFDA licensing in addition to BBR licensing because of the USFDA's historical and current role in the codification of Good Manufacturing Practices.

The US government recently passed the *Export Reform and Enhancement Act of 1996*, which provided a mechanism whereby a foreign institution could apply for exemption from the application of USFDA regulations for product that would be



returned to the originating country after being manufactured in the US. The Canadian Red Cross is in the process of submitting an application for exemption. The immediate goal of the exemption is to protect the security of supply for Canadians over the short term, by removing the risk that the USFDA could refuse to allow recovered plasma across the border.

Harmonization between US and Canadian regulatory policy is increasing. The BBR has adopted many of the standards and practices of the USFDA, so compliance with both regimes will become simpler to integrate over time.

## **Funding**

As in the 1980s, there continues to be a centralized funding mechanism to pay the Blood Program operator for its services. While the Canadian Blood Committee had imposed a line-by-line budget approval process, the Canadian Blood Agency brought in a global budget system. Though it was a positive step, a global budget system also had certain limitations, which were recognized by the parties involved.

The Master Agreement adopted a different approach based on a unit cost analysis. The process requires the Red Cross to submit an annual business plan, setting out the unit cost proposed with an explanation of the methodology. The Canadian Blood Agency then reviews the plan's reasonableness and cost-effectiveness. If the two are unable to agree upon a unit cost, the matter can be referred to an independent panel to perform a cost review to recommend a non-binding unit cost to the parties.

Since the Red Cross and CBA were unable to reach agreement regarding the plan for the 1996/97 fiscal year, the cost review panel was invoked. However, the panel did not fulfill its mandate in that it did not recommend a unit cost for consideration by the parties.

There is currently no agreement between the Red Cross and the CBA on how to approach costing. For historical reasons, neither party has much experience with a unit costing approach. It has also proven difficult to find agreed comparators--a blood program operating in a federal government system, over an immense geographic territory, as a sole supplier, and in two official languages. Governments and the CBA have refused any binding dispute settlement mechanism.

## **Risk Financing**

Any prudent organization must anticipate and make provision for funding of risks and claims arising from its activities - regardless of the nature of its operation. Over the years, risks of Blood Program operation have been financed by a combination of commercial liability insurance, a "pay as you go" understanding for the provinces and territories to reimburse such costs, and a more formal self-insurance structure.



Risk financing is a major issue for the Red Cross. Most transfusion activities in Canada today are insurable only on terms that make the purchase of insurance unwise. A self-insurance program instituted in 1992 is significantly underfunded, based on most recent assessments. The Red Cross is not only a non-profit organization, but any surpluses earned on operations are expected to be retained solely for the use of the blood program in subsequent years. It is obviously not possible for the Red Cross to cover such financial risk.

## **Public Health**

In the 1980s, there was little recognition that some blood transfusion issues were, in effect, a matter of public health. With today's heightened sensitivity to blood issues, some important linkages have been forged in some provinces, while others are less well developed. In Nova Scotia, for example, an arrangement to resolve difficult lookback investigations has been worked out. As soon as the Red Cross and hospitals have produced a list of recipients of an implicated unit or units, public health takes over and completes the lookback. A structured working group involving Red Cross, public health, and hospital representatives meets regularly to address common issues and concerns. The Canadian Liver Foundation and Red Cross have co-operated to produce a general hepatitis C education program.

At the federal level, Health Canada has formed a Blood-Borne Pathogens Division. As part of its mandate, it in turn established a Blood-Borne Pathogens Working Group. Red Cross was at first invited to participate in the work of this committee and then excluded, as it has been from all committees at the Laboratory Centre for Disease Control (LCDC). It is invited only to participate in large consensus conferences and consultations, at which a broad spectrum of users, laboratory and other scientific investigators are in attendance. While close daily working relationships exist, the Red Cross believes that the channel of communications between LCDC and the Red Cross should be formalized and not dependent on personal relationships.

## **5. Issues to be Resolved**

Many of the issues of the current blood system, from the point of view of the operator, evolve along the familiar axis of safety and cost. While the phrase "safety is paramount" is frequently used, experience indicates that the word "paramount" is highly qualified. Few would argue that the pool of funding is unlimited, and therefore every possible new approach to gain however small an incremental gain in safety, must be pursued. For how much safety is the Canadian blood system prepared to pay?

The problem with the Canadian blood system is not that this eternal question exists, but that the methods of resolving it are so imperfect. Policy, co-ordination and financing of blood operations, are all handled by the CBA, which itself is



tightly controlled by health ministries who are preoccupied with lowering costs. Safety standards are essentially established by the federal government, which itself plays no role in the funding of blood operations. The Red Cross is particularly constrained by the expectation that it will meet the full national demand for blood, but with no control over either funding levels or regulatory requirements, nor even access to binding arbitration. It does of course have control over the efficiency of its own operations.

Cost vs. safety trade-offs are matters of public health policy that can only be decided by governments. Evidence would indicate, however, that responsibility is often transferred to the Red Cross, the organization least empowered to take such decisions. Several methods are used to accomplish this:

- open-ended regulations to which there is no limit on the operator's requirement to pursue safety,
- extensive and often redundant bureaucratic processes that add little to the quality of the blood supply,
- unclear decisions or refusal to take decisions, thus forcing the operator to either interpret or to act without direction,
- delayed funding decisions,
- the demand for *perfect information*, which normally is manifested through repeated demands for more information or more studies, and
- through a variety of mechanisms that imply that *costs are too high*, with no commitment to test that conclusion through independent channels.

Whatever else may be done in the system, until governments develop a mechanism that can, and does, assume full and proper accountability for those decisions that can only rest with government, then the position of any operator of the blood supply program will be difficult.

There has been considerable discussion about the need to clarify roles and responsibilities within the Canadian blood system. That is agreed, but there is a critical second step--to ensure that the required authorities and resources are in place to fulfill those responsibilities.

## 6. The Future Canadian Red Cross Blood Program

The Canadian Red Cross has for a number of years invested significant energy in transforming its operations and structure to conform to the new manufacturing model or paradigm, with the following clear objectives; first, to increase the safety of products and processes; second, to enhance national security of supply; and, third, to achieve cost efficiencies. The first two objectives are virtually axiomatic, ongoing basic preoccupations of all responsible blood services. In the current era of cost-containment, the last is of equally critical concern.



Much discussion has taken place about the moves within the Red Cross blood program to tighten, strengthen, and standardize management. Unless the regulatory authorities of this country decide to turn back the clock to the regulatory environment of the 1980's, this discussion is academic. Modern quality standards can be achieved only by rigid adherence to approved processes, and in a national blood program all important processes must be standardized throughout the country.

Centralized control over the critical safeguards that protect the safety of the blood supply is absolutely essential. This is required to meet tougher regulatory requirements, to further standardize operations, to enhance the speed of response to change and to obtain cost-efficiencies where consistent with the commitment to continue to improve the safety of the blood supply.

#### Complex Nature of Operator's Role

Although the change to the new paradigm began much earlier, it was 1989 when the Bureau of Biologics of Health Canada extended the scope of its regulatory activity to include blood as well as blood products and proposed to license the Canadian Red Cross as a manufacturer of biologics. It has been argued that at that moment the blood program ceased being a part of the health care system, and became a *supplier* to the health care system.

This changed status has generally not been accompanied by any change in approach or philosophy by provincial health ministry officials who interact with the blood program. Solutions to existing problems that would not be favourably received treat the blood supplier essentially as a drug supplier. Preferred solutions lead to more complex systems and more bureaucratic entities designed to sustain traditional approaches to blood system operations. The recently completed Quebec Blood Supply System report perhaps bridges the gap when it clearly treats the blood system as part of the health care system, but proposes an approach to *suppliers* based on performance criteria and contracts.

At the very least, the blood supplier is a hybrid - a manufacturer of biologics from the viewpoint of the federal government regulator, a provider of healthcare services and products to its primary clients, the hospitals, and a humanitarian organization to its donors. Any re-organization of the Blood System must take into account this complex nature of the operator.

#### Blood Governance

The Board of Governors of the Canadian Red Cross has been examining closely the current structure of governance for the Blood Program. Under consideration are several variations of a separate board for the blood program. Its relationship to the rest of the Society could, for example, be along the same lines as that of the Board of Directors of the Canadian Red Cross Fractionation Corporation (FracCo).<sup>16</sup> Dealing with the F/P/T and Quebec government initiatives has temporarily diverted the Board from completing this work.

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<sup>16</sup> For a description of the structure of FracCo and its relationship to the Red Cross, see Appendix F.



**Regulatory Framework**

An integral element in the worldwide shift to the new model for blood services is a corresponding shift in the regulatory framework in which they operate. Many major blood services are at some point on the road to developing standard operating procedures (SOPs) based on current Good Manufacturing Practices (cGMPs). The goal is to improve safety through tightened management processes and continuous process improvement, in tandem with new, tighter regulatory requirements. The Canadian Red Cross response consists of the Regulatory Compliance Project, well on the way to completion for its target date at the end of 1999.

By that date, a new range of SOPs will have been developed, piloted and implemented across the country, thus moving all Centres to the cGMP environment. SOPs will be integrated with the computerized management information and process control system; and all employees will have been trained as part of the ongoing national training program, a regulatory necessity.

The cost of this project is budgeted at \$44.4 million and 116,000 staff days for Red Cross personnel. Critical to completion on time is the completion of the BBR review of the new SOPs and timely approval of the new computer systems, also by the BBR.

**Computerization**

Since 1989, when new computer system requirements for Canadian Red Cross Blood Services were defined, completion of another critically important project, which subsequently became known as CISCO, has been a constant and at times troubling preoccupation of the Canadian Red Cross. Management and funding of the project have posed major challenges. As already noted, it is, nonetheless, essential to success in the shift to the pharmaceutical manufacturing model and compliance with regulatory requirements, which together promise significant efficiency and safety benefits.

Creating a totally new system was made necessary by the absence of any existing combination of software and hardware that could be adapted to the needs of the Canadian Blood System. It will automate tracking of donor recruitment, blood collection, testing and processing, as well as product distribution; augment existing --largely manual--controls on the safety and security of the blood supply, and improve blood product processing. It has the future potential to link to hospitals, permitting direct order entry, inventory usage monitoring, and automatic donor to recipient tracking. Additional benefits may include automated performance measurement of various aspects of blood collection, processing, and distribution, as well as input to cost accounting.<sup>17</sup>

At present, software development and testing has been completed; SOPs are being adapted to the system; and training materials are under development. Field evaluation is currently in progress.

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<sup>17</sup> A more detailed list of the functions CISCO will perform, compared to the existing, outmoded BLIS system can be found at Attachment G.



**Management**

As part of the overall restructuring of Blood Services, internal organizational changes are intended to improve management and operational efficiency. The old structure was hampered by an extremely broad span of control for the senior blood program manager; different processes and policies in different blood centres; different quality and service levels; and a structural design that encouraged a certain resistance to the requirements of a cGMP manufacturing model.

The new model requires standardized operating practices including standard equipment, full-time management, expertise in and commitment to cGMPs, faster response and professionalism in donor service. Among medical and professional staff, current standards require a commitment to customer service, safer processes, knowledge of medical trends, well developed and co-ordinated non-manufacturing medical services, research and development capability, and enhanced product support. Cost efficiency calls for national inventory management, elimination of support services duplication, taking advantage of economies of scale, and transparency of the costing model.

In its new configuration, Blood Services has been divided into three regions; namely, Western, Central (Ontario), and Eastern (Quebec and Atlantic Canada). Each has a variety of facilities with different functions ranging from full-service Centres to collection units. Feasibility studies have been completed and regionalization of testing in a few centres across the country is about to commence. (As already noted, Quebec and Montreal have already rationalized a number of functions). Medical and manufacturing services are linked but separate, with qualified managers in charge of manufacturing operations and better use made of physicians' time and expertise. Performance indicators, already in place as recommended in the Management Report, will be further developed and formalized.

**Stand-Alone  
Plasma Centres**

Among the new, specialized facilities in the Regions, as already mentioned, five to seven USFDA-licensed free-standing plasma collection centres are planned by the year 2000. An operating licence was granted by BBR on September 10, 1996, to the first of these, located in Thunder Bay. The USFDA issued a registration number in April 1996, all documentation has been submitted and an on-site inspection by the USFDA is scheduled for January 1997. Testing is now taking place in Bayer's USFDA-licensed laboratories in the US until a Canadian Red Cross testing facility has been licensed by the USFDA.

## **7. The Future of the Blood System in Canada**

Having examined the major issues that impinge on the operator's ability to function efficiently and to promote safety within the system, the following is offered to assist the Commissioner in designing an improved Blood System structure that would ensure a timely, appropriate and reliable response to future threats to the safety or security of Canada's blood supply.



## Accountability

In its pure sense, to be accountable is *to be bound to give account* - to explain, to answer, to report. One who is accountable, is however normally considered also to be *responsible*. Increasingly this concept of responsibility translates into taking the blame for what may go wrong, whether or not it is truly within his or her control. Occasionally one might even get some credit, even if that also was truly beyond his or her control.

In complex systems, characterized by functions mandated by different authorities (i.e. a physician licensed by a professional college operating in a hospital licensed by a provincial health ministry using a blood product licensed by the BBR), while accountability in its pure sense can be vested in one person, placing responsibility in terms of rewards and punishments in one place is unjust.

Any discussion of accountability therefore requires precision along a number of lines. While not exhaustive, some of the more important components are:

- to whom is one accountable,
- for what is one accountable,
- is one mandated and resourced to fulfill the accountability, and
- what is the process by which one is held accountable?

In complex systems, it is unlikely that any one entity can be held truly accountable --the fabled single point of accountability. In the blood system for example, the head of a national blood authority could hardly be held accountable for a major failure by a supplier with a good track record or for the incorrect use of a blood product by a physician--despite the fact these two parties are part of the blood system as broadly defined.

It is more within possibility to hold one party accountable for a *process* that defines the various accountabilities, ensures they are understood by the parties involved, assesses the capacity of the party to fulfill its accountability, and monitors and reports regularly on the state of performance (accountability) in the overall system.

The Red Cross believes that accountability should be focussed first and foremost on clarifying the responsibilities and authorities of the various parties to the system. Only in terms of monitoring and promoting a coherent system of accountabilities, should a single point of accountability be considered.

Much useful work has already been done in the Master Agreement and the Supply Agreement to define the limited set of accountabilities that exist between the provinces (essentially as funder), the CBA (essentially as purchaser and agent for the provinces), and the Red Cross (operator). They have proven difficult for the Red Cross due to the inability, outside of the courts, to force issues to resolution. It is essential to establish a mechanism to break this deadlock in any new system.



## Key Functional Requirements

The Society believes that any solution to the current need to reform the Canadian Blood System must ensure that the Provinces and Territories will receive an adequate supply of safe and high quality blood products and services at the lowest cost compatible with safety requirements.

To achieve this goal, the federal government, through its regulatory agency, the Bureau of Biologics and Radiopharmaceuticals (BBR) must establish and monitor standards for the safety and efficacy of blood products, and ensure compliance with good manufacturing practices, based on international standards.

In order to allow it to fulfil its commitments to supply products and services within a context of reasonable risk, The Canadian Red Cross--or any other operator chosen--must then have the capacity:

- to operate according to its licence;
- to provide an adequate supply of products and services;
- to recover collection, processing and distribution costs;
- to be accountable for operations by exercising required responsibilities;
- to maintain donor support to ensure an adequate supply of blood, the essential raw material of the system; and
- to introduce improvements to quality and safety within the prescribed regulatory framework.

The ultimate objective is to ensure that the users of blood products and services (patients, doctors and hospitals):

- have timely access to the most effective and safest products and services to meet their particular needs; and
- have confidence in the adequacy and safety of the blood supply.

Last, but absolutely not least, blood donors, whose gift of life makes the voluntary blood collections system possible, must be able:

- to supply the raw material with a minimum of delay, inconvenience and pain;
- to trust that their gift will be used to save lives;
- to have their gift properly recognized; and
- to have confidence in the safety, efficiency and efficacy of the Blood Program.

## Key Operational Imperatives

Optimal performance can best be achieved if blood and plasma derivatives are treated in a fashion similar to that of all other pharmaceutical and biological products. The blood supplier must respond quickly to safety and efficacy concerns as well as provide an adequate supply of blood products on a daily basis. Once a



safety initiative is required, the blood supplier should not have to wait for an intermediary body to decide whether funds can be made available. Under these circumstances, the blood supplier must be able to implement changes in an expeditious manner and recover its costs.

The Society, therefore, recommends that the blood supplier should charge directly for products and services on a cost recovery basis. A variety of options are available for cost recovery for products used, including 1) directly from hospitals, 2) from the Provinces and Territories or 3) from the CBA or other central body. The clear advantages of billing hospitals directly are the transfer of economic choice to the point of use and the resultant encouragement it provides to use less expensive alternative products and technologies.

This was, in fact, the basis for the first model for the Blood System produced for public discussion by the Red Cross in 1993. This market-oriented model assumed that governments would retain their policy-making and regulatory function and no powerful blood authority would be needed. The governments' expectations of the supplier would be clearly spelled out through general policies, while the client's expectations would be spelled out in the contractual agreements. A small staff secretariat might be created to advise ministers on policy requirements and to monitor broad policy implementation. Otherwise the blood supplier(s) would be treated as would any other pharmaceutical manufacturer supplying products to public hospitals.

Under a system of cost recovery, the blood supplier would negotiate supply contracts with the designated source of payment for the provision of products and services, preferably the hospitals, as follows:

- the cost of fresh products to be recovered on a cost per unit basis with an appropriate credit for plasma used for fractionation;
- the cost of fresh product development to be included in the unit cost of fresh products;
- the cost of clinical consultation services to be included in the unit cost of fresh products;
- the cost of fractionated products to be recovered through the sale of these products, but with the market open to alternative suppliers (consistent with government policy on issues such as volunteer donors); and
- the cost of other clinical laboratory services to be negotiated with the Provinces and Territories or hospitals on a contract basis in an open competitive environment.



Under such a system,<sup>15</sup> the Provinces and Territories would naturally require assurances of “value for money” when costs are automatically passed through in a non-competitive situation; i.e. for components. The proposed pricing structure would, therefore, have to be subject to review, in the case of disagreement, or on an ongoing basis, by an independent fair-price tribunal, for example, the Patented Medicines Price Review Board. Since it already exists and governments have experience working with it, why not extend its use for this purpose?

#### Description of the Model & its Major Benefits

While the Quebec Report is quite consistent with the approach proposed by the Red Cross in 1993, the announcement arising out of the F/P/T initiative indicates that the other governments of the country prefer a more traditional approach to current problems by relying on more traditional governmental solutions—in this case, the creation of a central authority with substantial powers.

Many different systems operate successfully around the world. There is no single perfect solution. On this basis, Red Cross developed its own structure based on the announcement by ministers that they intended to establish a national blood authority. The model is shown in Figure 2.

In this model the National Blood Authority (NBA) would be responsible to the Conference of Health Ministers. The Federal Minister of Health would subsequently be responsible to Parliament for the actions of a single authority, established by federal legislation and called the National Blood Authority (NBA). The Conference of Health Ministers approves major policy recommendations from the NBA and Provincial and Territorial Ministers of Health would be responsible to their respective legislatures for policies approved by the Ministers.

The functions of the NBA would be the following:

- to assess and recommend policy to the Conference of Health Ministers;
- to set overall objectives for the Blood System;
- to receive reports and monitor performance in achieving objectives;
- to promote co-ordination and co-operation among all elements of the Blood System;
- to provide a forum for the discussion of blood-related issues.

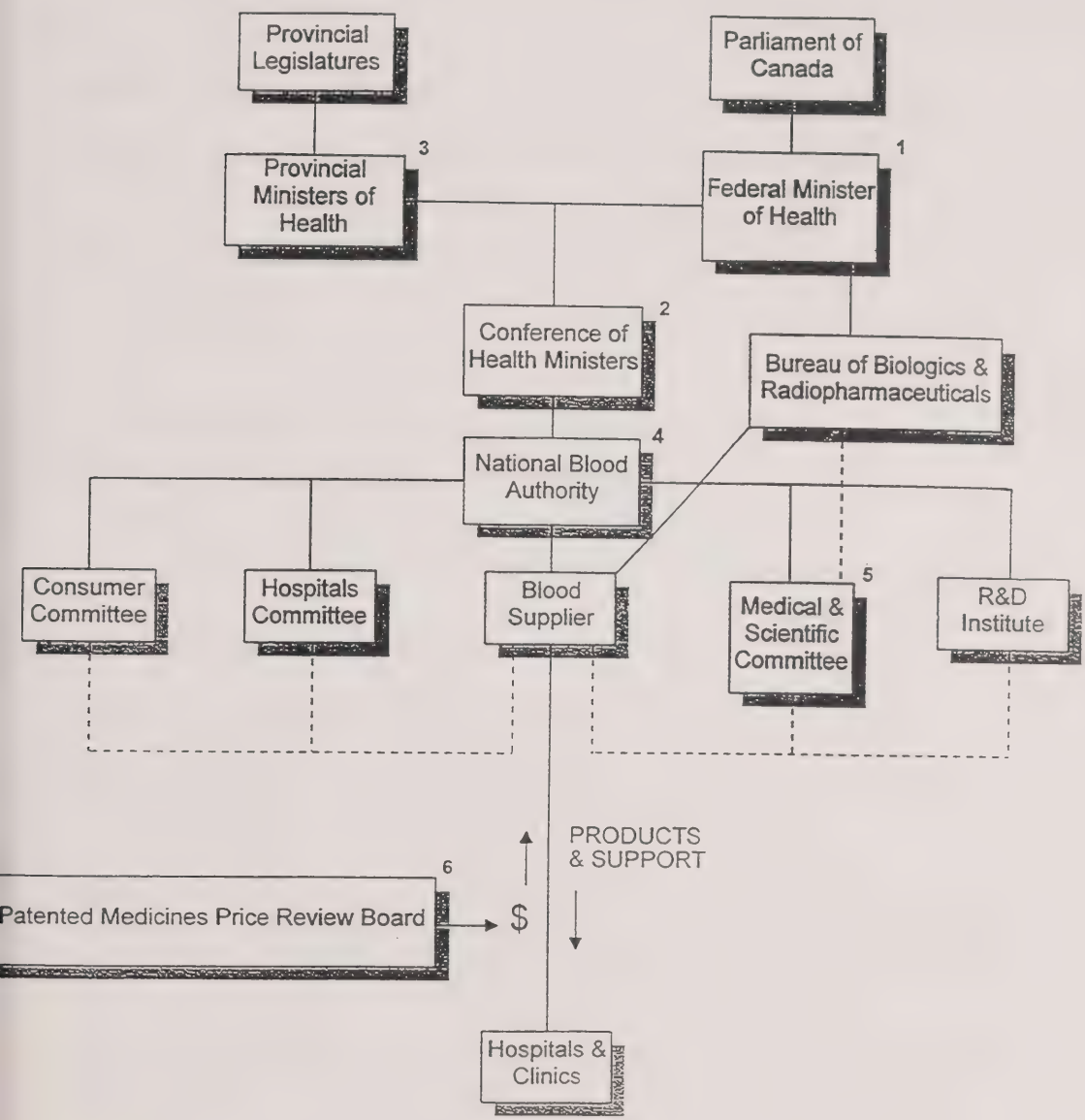
In addition, a Medical and Scientific Committee (MSC) would report to the NBA, but could also serve as a common committee for the regulator, the BBR, the Consumer Committee, and for the blood supplier. Actions taken by the blood supplier in accord with recommendations of the MSC would be considered as consistent with policies made by the Conference of Health Ministers, until such recommendations were formally approved or changed by the Conference. This would contribute significantly to the objective of a quick response capacity.

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<sup>15</sup> See Figure 2.



# PROPOSED STRUCTURE OF THE CANADIAN BLOOD SYSTEM



See notes on next page.

FIGURE 2



## **Proposed Structure of the Blood System (cont.)**

### **Notes:**

1. Minister of Health is responsible to Parliament for the National Blood Authority.
2. Conference of Health Ministers approves major policy recommendations of National Blood Authority.
3. Provincial and Territorial Ministers of Health responsible to their Legislatures for policies approved by Ministers.
4. Functions of National Blood Authority:
  - to assess and recommend policy to the Conference of Health Ministers
  - to set overall objectives for the Blood System
  - to receive reports and monitor performance in achieving objectives
  - to promote co-ordination and co-operation among all elements of the Blood System
  - to provide a forum for the discussion of topical issues

Authority to be established by federal legislation.

5. Medical and Scientific Committee (MSC) would report to National Blood Authority, but would also serve as common committee for BBR (regulator), Consumer Committee, and blood supplier/operator.

Actions taken by blood supplier in accord with recommendations of MSC would be considered as consistent with policies of Conference of Health Ministers (CHM) during interim period until such recommendations formally approved or changed by CHM.

6. Blood components and products to be treated as drugs, subject to the review of the Patented Medicines Price Review Board.



Advice and information to inform its decisions could be obtained from a Consumer Committee. An R&D Institute would provide co-ordination and a clear focus for research truly responsive to the needs and priorities of the Blood System in Canada. Finally, the Hospitals Committee would provide input from the point of view of the principal users of blood products and services.

In addition to defining the composition of the board of the NBA, legislation would outline the legal, financial and public accountability for all aspects of safety. The authority would reflect no meaningful improvement on the existing system if it did not have some legislative authority to approve funding to ensure safe operations and a secure supply. It would be necessary to further define the authority's overall accountability by contractual obligations with other parties, particularly with the suppliers.

The accountability of each party would then be, through the NBA, to the Conference of Health Ministers, and, in turn, to Parliament and the Provincial Legislatures. Each of the partners would be effectively held accountable for its own activities, recognizing that, not only the supplier, but all parties have a role to play in making blood products and their use as safe as possible.

## Funding & Prices

On the issue of providing adequate funding for the blood supplier, if cost recovery were to be achieved at the hospital level, this model would also remove the requirement for the provinces as a group to be directly involved in the process of authorizing payment for products already licensed by the BBR. Once a product had been accepted into the formulary of a particular province (if required), this arrangement would leave the decisions on product choice and volume in the market place with the existing cost control mechanisms of the healthcare sector. This would allow more choice for individual Provinces and hospitals and help ensure that they receive the best value for each healthcare dollar spent on blood products. In addition to providing more appropriate controls on product utilization--and therefore costs--the model also places the decision on product choice closer to the point of treatment, where the most appropriate medical decisions can be made.

The establishment of product prices by the blood supplier would place the Blood Program in a competitive environment, in which comparisons could be made with other biological manufacturers and transfusion services around the world. Indeed, this is exactly the basis for the determinations made by the Patented Medicines Price Review Board, which is proposed as an appropriate body to review the prices of blood components and products.

Operating the Blood Program in such a competitive and entrepreneurial business environment would enhance the blood supplier's ability to make strategic decisions concerning the allocation of resources to operations, capital improvement, and research and development. A business approach to strategic planning and resource allocation, with all required safety provisions, would create the appropriate environment within which the Blood Program could develop and



maintain the investments in high quality products and services that will be required to meet Canadian needs in the future.

In the United States, the United Kingdom, France and elsewhere in Europe, not-for-profit blood centres bill the hospitals for products and services supplied. The case in the United Kingdom is of particular interest. Until 1992, UK blood centres were funded directly by the government, as is done now in Canada. Subsequently, the funding arrangement in the UK was changed to allow blood centres to recover their costs by billing hospitals directly. As a result, the UK Blood Program remains government funded by an indirect mechanism through the hospitals. These changes were instituted following an in-depth study. Their objectives are to improve efficiency, contain costs and control product utilization.

#### **Financial Assistance for those Harmed by the System**

There is also a need for a mechanism of financial assistance for those harmed by treatment with blood or blood products. Since these are biologically derived products, they will never be 100% risk-free.

The only current venue for relief of individuals who have been harmed by the Blood System is the tort system, even though blood is known to carry inherent risks. Litigation can cost far more than money to both sides in a dispute. The harmed person must tolerate a lengthy, extensive and intrusive court process, with a very real prospect of failure at the end of it. Those involved in blood service operations--including the front-line individuals who keep the Blood System running day by day--spend a great deal of time in preparing the defence of each litigation case.

In effect, the current system finances all anticipated and unanticipated risks of the blood supply either on the shoulders of the individual patient, or on one or more institutions involved in the Blood System. The attached analysis entitled "Financial Assistance for Blood-Related Injuries" explores the implications of this "all or nothing" approach in depth, and examines various models which provide an alternative to fault-based compensation for parties who suffer the risks of the Blood System. A combination of what is called in the US "blood shield" legislation and no-fault financial assistance is recommended.



## 8. Conclusion

Whether or not the Canadian Red Cross continues to play the role of blood supplier/operator of the Blood Program, the Red Cross of the 1990s is a different organization from that of the 1980s. New conditions and new challenges, combined with a determination to strengthen a system that was not prepared for the infiltration of AIDS into the blood supply, have transformed how it does things, how it is organized, and how it thinks. The Red Cross or any new blood supplier is not the whole Blood System. The supplier must work with and be supported by its other partners. These partners include governments, the regulator, hospitals, physicians and community groups. A co-operative approach will best achieve the structural transformation required to earn again the full confidence of the Canadian people.

The Interim Safety Report found that there was no comparable Blood System safer than Canada's, but that it was vulnerable. Over the coming decade, the goal of the blood supplier, as an integral part of the Blood System in this country, must be to convince the Canadian public by action that there is no stronger, safer or more efficient system than ours.

In 1996 we are at a crossroads for the Blood System in Canada. There is no single way to resolve the structural, governance and accountability problems of the past. Resolved they must be, however, without delay or we risk losing the advances we and our partners have made since the tragic events of the 1980s. Whatever solution is chosen must reflect the Canadian reality and values that underlie our cherished national health system.





**America's Blood  
Centers**

SERVING COMMUNITIES NATIONWIDE

# A B C N E W S L E T T E R

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

1996: #40

October 18, 1996

## Blood Safety Director Stresses Importance of Restoring Public Confidence in Blood Supply

"My serious message to you today is that blood product and service providers share with the Federal government the very difficult challenge of restoring public confidence both in the safety of the nation's blood supply and in our ability to respond to new threats to blood safety," Philip R. Lee, MD, Assistant Secretary for Health, said this week during the National Affairs Symposium at the American Association of Blood Banks' annual meeting in Orlando, Florida. Dr. Lee also chairs the new HHS Blood Safety Committee, which comprises the heads of the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health and the Health Care Financing Administration.

### INSIDE:

AABB Board Reaffirms  
Association's Role in  
Standard Setting;  
Increases Opportunities for Public  
Comment

CBER to Require  
Warning Labels on  
Plasma Derivatives;  
Require Monthly  
Reporting of  
Infectious Disease  
Transmission

NHLBI Cord Blood  
Transplantation Study  
Begins

"Without a doubt, the current environment has been defined mainly by reaction to the tragedy of HIV transmission by blood and blood products," Dr. Lee said. Because of HIV, "the public has come to fear blood to a degree out of proportion to the actual known risks . . . and shows unwillingness to accept even small risks when they affect blood products," he said. "Underlying these attitudes is the enduring memory that the products were promoted as safe in the early 1980s when they were not, and that the involved health professional industry and the government did not interdict the dreaded threat of HIV until after many thousands of infections had already occurred."

**"In sum, the fear of blood is really the fear that a similar tragedy could happen again, without warning and despite the assurance of experts," Dr. Lee said.**

Dr. Lee focused his presentation on the need for continuing improvements in blood safety standards and restoring public confidence in the nation's blood supply, stating that decisions made during the early 1980s still affect the public's impression of blood safety today. Noting that while the public has great faith in technology, in reality "we cannot eliminate all transfusion risks." He called on the government and the blood services community to make a collective effort to establish "a new foundation of confidence based not on zero risk but on the honest communication of risk" and by showing that public and private agencies are working together to continue to reduce this risk. "Confronting this challenge requires sober self-assessment and some rethinking of roles, responsibilities and organizational structures," he said.

(continued on page two)



Phil Lee Addresses AABB (continued from page one)

HHS now has formally approved the formation of an outside Advisory Committee on Blood Safety and Availability, Dr. Lee reported. During a 21-day period, expected to be posted in the *Federal Register*

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*"If public trust is not restored,  
the pressures on us all will be  
unrelenting despite any real  
advances."*

*—Philip Lee, MD*

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this week, HHS Secretary Donna Shalala, PhD is seeking nominations to this advisory committee from medical and legal experts, economists, sociologists, ethicists, and consumer and industry representatives. The purpose of this Advisory Committee will be "to address the concern over inputs from outside government" and "to deal with social, legal, ethical and economic aspects of decision making that affect blood policy." He contrasted the role of the new committee with that of the Blood Products Advisory Committee. For example, the Blood Products Advisory Committee would typically be asked whether a set of clinical

trial data were adequate to support safety and efficacy of a new product under FDA review. In contrast, the new committee might be asked "whether cost-effectiveness is a legitimate standard to apply to the evaluation of a potential new donor screening test."

Dr. Lee went on to discuss the steps HHS is taking to improve blood safety and public confidence by commenting on the recommendations outlined by two investigations: IOM's July 13, 1995 report "HIV and the Blood Supply: An Analysis of Crisis Decision Making," and the August 2, 1996 report of the Congressional Committee on Government Reform and Oversight entitled, "Protecting the Nation's Blood Supply from Infectious Agents: The Need for New Standards to Meet New Threats."

According to Dr. Lee, the IOM study "made many findings of missed opportunities to intervene and save lives earlier in the AIDS epidemic" but the study "found no evidence of wrongdoing by government officials." The IOM study determined that an important lesson learned from the 1980s was that there must be more communication and an improved decision-making process to assure a more rapid and efficient response mechanism. HHS created a task force to review the IOM study recommendations—which subsequently reported its response at a hearing before the House Subcommittee on Human Resources and Intergovernmental Relations in October.

Of the fourteen IOM recommendations, thirteen have been chosen by Dr. Shalala for implementation, Dr. Lee said. The exception is the establishment of a no-fault compensation system, considered by the task force to "lay outside of the purview and expertise" of HHS and to fall under Congressional responsibility. Dr. Lee stated that the Congressional recommendations for "Congress to establish the Blood Safety Committee and the Advisory Committee on Blood Safety and Availability in statute and for Congress to establish an indemnification system for blood injuries as recommended by the IOM study" would "necessarily be left to the Congress."

(continued on page three)



Phil Lee Addresses AABB (continued from page two)

**HCV Lookback.** Referring to the Congressional recommendation that the estimated 300,000 living recipients of blood and blood products infected by hepatitis C prior to 1990 be notified of their potential infection, Dr. Lee said "I have directed the CDC to develop and disseminate risk information and intervention messages." But the question of 'lookback' notification of blood recipients based on subsequent testing of the donor has been deferred for discussion at the PHS Advisory Committee, he said, citing the many concerns that have been raised about limited effectiveness of such procedures and due to the fact that transfusion acquired infections represent a small part of the estimated 3.5 million chronic infections by hepatitis C in the US.

**Broader Role for CDC.** Two other key recommendations of the IOM was that CDC's capability to detect, monitor and warn of adverse affects in blood and blood product recipients and the need for increased responsiveness of HHS to findings of the CDC early warning system, Dr. Lee said. HHS has addressed these recommendations by appointing a blood coordinator, Rima Khabbaz, MD, to "assure a consistent focus on blood issues within the complex CDC organization." In addition, CDC has greatly expanded its activities both through surveillance and special studies of particular diseases and populations, including an emphasis on emerging agents. CDC also participates on the Blood Safety Committee and, for the first time, by having a CDC representative seated permanently on the Blood Products Advisory Committee, Dr. Lee pointed out.

**Great Expectations for the Blood Services Community.** Emphasizing the blood industry's role in improving blood safety and restoring public confidence, Dr. Lee noted, "it is the industry which has the responsibility to make products which meet current standards that assure safety, purity and potency." He continued by stating that "it is a prevailing assessment of FDA regulators that much of the blood industry is not measuring up to these standards." He pointed out that "roughly three fourths of blood collected currently in the US is obtained from establishments operating under a court-ordered Consent Decree of Injunction."

Dr. Lee closed by highlighting the fact that as technology advances, standards for blood safety continually are being raised. However, "if public trust is not restored, the pressures on us all will be unrelenting despite any real advances," he concluded. □



## Whither the Blood Products Advisory Committee?

M.H. SAYERS

DURING THE EARLY 1960s, the Food and Drug Administration (FDA) began appointing advisory committees to help with drug evaluations. Later, in the 1970s, committees were formed to review biologics and assist with the classification of medical devices. These committees, about 40 of which currently provide input to the Centers for Biologics Evaluation and Research, for Drug Evaluation and Research, and for Devices and Radiological Health, are subject to the provisions of the Federal Advisory Committee Act of 1972. This Act was intended to put to rest concerns that Congress then had about the way in which committee meetings were being conducted. In the first place, because deliberations were closed, there were legitimate criticisms that important issues bearing on public well-being were often resolved in private discussion. Second, in a complaint that has been revisited recently, at least as far as the Blood Products Advisory Committee (BPAC) is concerned, too many of the appointees to committees were regarded as bringing to the table an unacceptable industry bias. In this latter regard, the Code of Federal Regulations is clear in stipulating that an advisory committee "serves as a source of independent expertise and advice rather than as a representative or advocate for any particular interest."<sup>1</sup>

The extent to which FDA advisory committees have been the focus of congressional reports over the past 25 years is a reminder that experts on the committees, ostensibly bent on helping the agency develop guidelines about scientific and technical issues, are naive if they assume that their activities are immune from political influence. Those conceding that such influence prevails should also bear in mind that, just as the opinion of the electorate is shifting and restless, so also is the will of Congress predictably inconstant. A scant 4 years after the Federal Advisory Committee Act was passed, a different Congress decided that it was the FDA, rather than industry appointees, who were perverting the purpose of advisory committees. In 1976, the House Committee on Gov-

ernment Operations issued a report entitled "Use of Advisory Committees by the Food and Drug Administration," which recommended a degree of autonomy for advisory committees so that they could be permitted "to arrive at independent scientific findings without further intervention by FDA to influence their judgment on the basis of non-scientific considerations."<sup>2</sup>

Echoes of this theme were heard later, in a report from the Commission on the Federal Drug Approval Process.<sup>3</sup> Although this commission's recommendations mainly concerned the drug review process, some provide interesting counterpoints to events shaping BPAC's current composition and responsibilities. In particular, the commission proposed that the FDA commissioner request from the Department of Justice "a less restrictive interpretation" of the Federal Conflict of Interest Statute, arguing that a broader use of experts would enhance the efficiency of review processes. A subsequent report from the Department of Health and Human Services (DHHS) Advisory Committee on the FDA,<sup>4</sup> released in 1991, also carried a message about the composition of advisory committees. The report urged that the commissioner "must be empowered, to the limits of statutory authority, to manage the FDA scientific and technical personnel, and to improve the FDA's access to scientific expertise including advisory committee appointments."<sup>4(p v)</sup> Reference was also made to conflict-of-interest issues, and the agency was encouraged to reduce the extent to which conflict of interest was an obstacle to participation in advisory committee activities.

Against this background of congressional oversight of the FDA, the Institute of Medicine (IOM), a nonlegislative body, has emerged over the last few years as another source of scrutiny. The institute's first foray was in 1991, at the request of David A. Kessler, MD, who was then the chairman of the Subcommittee on Drugs and Biologics of the DHHS Advisory Committee on the FDA. He asked the IOM how the FDA could make better use of advisory committees and how they could be used in relation to agency management and accountability. His questions were prompted by evidence he had heard at the IOM's Forum on Drug Development that challenged the credibility of the advisory committee system.

A specially appointed IOM group, the Committee to Study the Use of Advisory Committees by the FDA, was convened. It included experts in academic medicine, nursing, regulation, health care financing and delivery,

Abbreviations: BPAC = Blood Products Advisory Committee; DHHS = Department of Health and Human Services; FDA = Food and Drug Administration; HIV = human immunodeficiency virus; IOM = Institute of Medicine.

From Transfusion Surveillance, Puget Sound Blood Center, and the Department of Medicine, University of Washington, Seattle, Washington.

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and health policy research. In addition to responding to the questions posed by Dr. Kessler, who was by then the FDA commissioner, complementary objectives were developed that included providing guidance about the selection of advisory committee members, analyzing their potential for financial conflict of interest and intellectual bias, and recommending how the FDA could ensure the independence of its advisory committees.

The group's final report, which was published in 1992,<sup>5</sup> included more than three dozen recommendations covering topics as diverse as nomination criteria, recruitment procedures, the timely availability of materials, and the practice of "custom tailoring" the composition of advisory committees with appointees likely to favor FDA opinions. Many of the proposals are still germane. One had to do with the question of "balance" in the membership of advisory committees. Although the Federal Advisory Committee Act had made this a requirement, the Act provided meager instruction on how to achieve the goal. The IOM group took the opportunity to define the term. They emphasized that balance should be interpreted as "a mix of relevant scientific disciplines and a diversity of scientific views."<sup>5(p19-20)</sup> The group had considered an alternative interpretation of balance, which would be achievable, for example, by appointing "representatives (or advocates) of specific constituencies, irrespective of scientific competence,"<sup>5(p120)</sup> but they rejected this proposal, believing that "the primary role of advisory committees is to provide the agency with the best scientific interpretations and advice and not to represent specific constituencies."<sup>5(p120)</sup>

Three years after the report on FDA advisory committees, a different IOM group, the Committee to Study HIV [Human Immunodeficiency Virus] Transmission through Blood and Blood Products, also issued a report.<sup>6</sup> Their findings were the result of a request by DHHS that the IOM examine decisions made from 1982 through 1986 affecting the safety of transfusion during the emerging HIV epidemic. The authors conducted an extensive year-long analysis and submitted a number of proposals designed to improve the decision making needed to meet future infectious challenges to the blood supply. Some 10 days before the report was made public, the FDA commissioner released 10 of the 15 regular voting members of the BPAC. Although the reasons were not announced, all the dismissed members had in common an academic, employment, or research affiliation with blood or tissue banking programs. The suspicion that their release was intended to deflect anticipated IOM criticism of the FDA was heightened when the IOM report did find fault with the agency for being "too reliant upon analyses provided by industry-based members of the Blood Products Advisory Committee."<sup>6(p15)</sup> The report went on to suggest that BPAC members involved in policy recommendations should be free of any true or apparent conflict of interest

and that balance should be ensured by a proper representation of members connected with the blood and blood products industry and those independent of industry.

If evidence for conflict of interest did, in fact, account for the release of industry-affiliated BPAC members, then the FDA did not take the opportunity to underscore the justification for dismissal with evidence of "tainted" advice from the group. What is more, none of the departing appointees had been a member of any of the advisory committees from 1982 through 1986 whose activities had been reviewed by the IOM. While specific examples of conflict were not revealed, the problem had been on the commissioner's agenda for a number of years. The IOM committee that reported on FDA advisory committees in 1992 attributed to Dr. Kessler the remark, "[I]f the committee does nothing else but solve conflict of interest problems, then we will have been well served." Although the IOM group expected to be given a detailed picture of the problem, none was forthcoming and no evidence was uncovered indicating that advisory committee members contributed to decisions in which they had significant personal financial interests.

It seems more likely that the BPAC was cleansed of blood- and tissue-banking community influence for political reasons than because of egregious advice that those members had given to the FDA. Commentary about the pressure Congress was putting on Dr. Kessler to reconfigure the BPAC had emerged more than a year before the 10 voting members were released from the BPAC. Senators Graham, Glenn, and Goss wrote to Dr. Kessler urging that consumers be nominated to the BPAC in a voting capacity. The senators suggested that this would force the committee "to recognize the consumers' views—and lives—as a necessary consideration in the process of ensuring blood product safety."<sup>7(p81)</sup> The implication that committee members, presumably as a consequence of their appointment to the BPAC, were subsequently exempt from ever becoming transfusion-dependent consumers themselves came as a hollow allegation, especially to those appointees, including the BPAC chairmen, who during the December 1994 BPAC meeting described their own experiences as recipients of blood components or derivatives.<sup>8</sup>

Political pressure also came, more recently, from the chairman of the Subcommittee on Human Resources and Intergovernmental Relations of the Committee on Government Reform and Oversight, who wrote<sup>9</sup> to Dr. Kessler reminding him that "decisive action" on his part was "long overdue" and making specific suggestions about how Dr. Kessler should manage the BPAC in the wake of the committee's recommendation against HIV type 1 antigen screening of volunteer blood donors. The suggestions included the immediate licensing of HIV-1 antigen tests for donor screening and the immediate disbanding of the committee and the replacement of one-third of the



total membership by "individuals who have received blood products (but not in connection with a professional or commercial activity) and representatives of consumer organizations with expertise in blood products."<sup>9(p14)</sup> In his letter to Dr. Kessler, Chairman Christopher Shays pointed out that his recommendations that some BPAC appointees must have consumer qualifications were included in a bill, HR 1021,<sup>10</sup> of which he was a cosponsor. Ironically, he made no mention in his letter of HR 1022, another bill that he cosponsored, that would "focus national economic resources on the greatest risks to human health, safety and the environment through scientifically objective and unbiased risk assessments and through the consideration of costs and benefits."<sup>11</sup> It was just such a consideration that had contributed to the BPAC's recommendation against antigen testing of donors.

Although it might seem appropriate to write an epitaph for those BPACs that drew from the ranks of the regulated to give advice to the regulators, the temptation should be resisted. Different legislatures have embossed advisory committees with very different features, which is not surprising if one bears in mind that the pendulum of political intent swings through a very wide arc. Some years ago, believing that advisory committees were hampered by FDA dominance and a disregard for science, Congress suggested a corrective course that insisted on scientific input. Although the most recent correction—namely, the emphasis on consumer input—may seem contradictory, it was probably inevitable, especially in the light of the 1995 IOM report on the early history of HIV and the blood supply, which included a criticism that "blood bank officials and federal authorities consistently chose the least aggressive option that was justifiable."<sup>5(p6)</sup> Current political distrust for industry advice could reflect an unfortunate residual suspicion that the alleged laxities in donor screening during the early 1980s persist today in the industry's failure to promptly embrace HIV antigen screening of volunteer blood donors or even to express tepid enthusiasm for the strategy.

The importance of the national blood supply is not contested, but an outside observer could be pardoned for coming to the dismaying conclusion that those responsible for maintaining the inventory—namely, blood bankers—and those regulating the practice—namely, the FDA and influential politicians—are indeed contestants. On the one side are blood bankers representing the more conservative opinion that cautioned against mandating costly interventions to prevent that which has not happened, such as transfusion-transmitted Creutzfeldt-Jakob

disease, or that which could happen (albeit rarely), such as window period transmission of HIV. On the other side are the politicians, apparently more inclined to pursue absolute safety by insisting that the FDA invoke stricter screening and additional testing of donors. In this context, it is chilling to consider that hypothetical risk is now subject to regulation, especially because transfusion recipients are heir to innumerable hypothetical risks. There are limits to how successfully recruitment can replace the donors that continue to be lost as a consequence of questioning and testing that convey little, if any, incremental improvement in transfusion safety. What is more, replacement first-time donors are less desirable, at least as measured by their prevalence of markers for infectious disease, than regular donors.<sup>12</sup>

The real risk is that the political imperative will prevail, rendering safe donors uncommonly scarce and the blood they provide prohibitively expensive.

## References

1. 21 CFR 14.1(b)(5), revised as of April 1, 1995.
2. US House of Representatives Committee on Government Operations, Use of Advisory Committees by the Food and Drug Administration. 11th report, based on a study by the Intergovernmental Relations and Human Resources Subcommittee, 94th Congress, 2nd Session, Report No. 94-787, January 26, 1976.
3. Commission on the Federal Drug Approval Process. Final Report. Washington, DC, March 31, 1982.
4. US Department of Health and Human Services. Final Report of the Advisory Committee on the Food and Drug Administration. Washington, DC, May 1991.
5. Rettig RA, Earley LE, Merrill RA, eds. Food and Drug Administration Advisory Committees. Committee to Study the Use of Advisory Committees by the Food and Drug Administration, Division of Health Care Policy, Institute of Medicine. Washington: National Academy Press, 1992.
6. Leveton LB, Sox HC Jr, Stoto MA, eds. HIV and the blood supply: an analysis of crisis decisionmaking. Washington: National Academy Press, 1995.
7. Zachary GP. Users want say in oversight of blood supply. Wall Street Journal, June 10, 1994; Sect B:1.
8. Transcript of the 46th Meeting of the Blood Products Advisory Committee. December 15-16, 1994.
9. Forum: HIV-1 p24 antigen testing and the safety of the blood supply. CCBC Newsletter July 28, 1995:13-5.
10. Congressional Record 1995;141(No. 34):H2176.
11. Congressional Record 1995;141(No. 34):H2177.
12. Starkey JM, MacPherson JL, Bolgiano DC, et al. Markers for transfusion-transmitted disease in different groups of blood donors. JAMA 1989;262:3452-4.

Merlyn H. Sayers, MB, BCh, PhD, Associate Professor, Department of Medicine, University of Washington; and Director, Transfusion Surveillance, Puget Sound Blood Center, Seattle, WA; current address: President and CEO, Blood Care, 9000 Harry Hines Boulevard, Dallas, TX 75235. [Reprint requests]



### FDA Issues Proposed Amendments to Drug GMPs; Seeks Harmonization of Quality Standards with ISO 9000

Proposed amendments that would clarify certain manufacturing, quality control, and documentation requirements and which would ensure that federal regulations more accurately encompass current good manufacturing practices (cGMPs) were released by the Food and Drug Administration (FDA) in the *Federal Register* on May 3, 1996. The requirements for process and methods validation are also being updated to include previously issued guidance, the agency said. The proposed revisions would amend some requirements, define or redefine certain terms, and clarify industry obligations regarding several portions of the regulations. The agency also is proposing to revise laboratory control and cross-contamination requirements and to clarify proper testing procedures.

**Basis of cGMP Regulations.** According to FDA, the cGMP regulations are based on three fundamental concepts of quality assurance: (1) quality, safety, and effectiveness must be designed and built into a product; (2) quality cannot be inspected or tested into a finished product; and (3) each step of the manufacturing process must be controlled to maximize the likelihood that the finished product will be acceptable. For the cGMP regulations to achieve their purpose, they must be periodically reassessed to "identify and eliminate obsolete provisions" or modified to reflect the current level of quality control due to technological advancements that a majority of manufacturers have already adopted, FDA said. The agency emphasized, however, that for a given practice to be considered a current good manufacturing practice it does not need to actually be in use by a majority, or even a specific percentage, of the industry.

There are a number of reasons why FDA has determined that revisions of the cGMP regulations are necessary at this time. According to the agency, rapid changes in technology have created situations that were not anticipated when the cGMP regulations were originally written; enforcement and litigation experience has revealed a "persistent lack of understanding" among a limited number of manufacturers regarding cGMP regulations; and FDA investigators have encountered serious validation deficiencies at a number of regulated firms.

**ISO Compatibility.** The proposed rule also notes that there are other organizations which have developed standards to define quality in the manufacturing process. One of these is the International Organization of Standardization (ISO). "The purpose of the ISO 9000 Standards is to provide generic guidance on quality in manufacturing processes to both industry and vendors supplying industry," the FDA said. These standards are applicable to any industry—they are not specific to the pharmaceutical industry—and compliance is voluntary. "The principles and practices elucidated in the ISO standards are not in conflict with those provided by cGMP regulations," the agency said. "Indeed, the voluntary ISO standards share common principles with FDA's cGMP requirements."

The proposed rule would amend or revise a number of cGMP provisions as follows:

- **Process Validation.** Process validation would be defined as a "quality assurance function that helps ensure drug product quality by providing documented evidence that the manufacturing process consistently does what it purports to do." The new regulations would specify the nature and extent of validation that would be necessary to ensure the identity, strength, quality and purity characteristics of the resulting products.
- **Methods Validation.** The proposed rule would define methods validation as "the documented, successful evaluation of an analytical method that provides a high level of assurance that such method will consistently yield results that are accurate within previously established specifications." Methods validation is central to ensuring the reliability of all evidence that supports a product's identity, strength, quality and purity.

(continued on page six)



Drug GMPs (continued from page five)

- **Contamination.** FDA is proposing to expand the contamination control requirements to encompass sources of contamination that even in small amounts may be potentially toxic to humans or animals.
- **Testing.** So all manufacturers are applying the same minimum standards and so that all manufacturers are thoroughly assessing test results and discrepancies to ensure all drug products are safe, the proposed rule would amend procedures for the testing of components, calculation of yield, and blend testing.
- **Quality Control.** To ensure that validation procedures are current, the quality control unit would be responsible for reviewing changes in product, process, equipment, or personnel and for determining if and when revalidation is required under the proposed rule.

Written comments on the proposed rule should be submitted to FDA by August 1, 1996. CCBC members and *Newsletter* subscribers may request copies of the May 3 proposed rule on current good manufacturing practice requirements from the CCBC office by FAX or postal mail (please specify). □



# News Briefs

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## AABB Board To Consider Changes To Standard-Setting Activities

In light of the potential risk to the AABB imposed by the decision in *AABB v Snyder*, the Board of Directors is considering significant changes to AABB's standard-setting process. Any or all of the following options will be considered and may be adopted by the AABB Board at its October Meeting. AABB members should consider each option carefully and communicate their comments and concerns to the Board.

### Background

At its meeting in July, the AABB Board of Directors reviewed the potential impact of the New Jersey Supreme Court decision in *AABB v Snyder*. The court determined, among other things, that, based on a variety of factors such as the "devastating" nature of the risk of transfusion-transmitted AIDS in 1984, the AABB's perceived "control" in 1984 over at least some New Jersey blood banks and the New Jersey Department of Health's "deference" to the AABB, the AABB owed a duty of ordinary care to persons receiving blood from its members. The court then affirmed a jury decision that the

AABB breached that duty of care to Mr. Snyder by enhancing the risk that Mr. Snyder would contract HIV from AABB's failure to recommend (or oppose) surrogate testing.

Despite the considerable risk for the AABB now associated with standard-setting and accreditation-related activities, the Board reaffirmed the AABB's commitment to both of these activities. In reaching this decision, the Board considered, but rejected, the options of (a) ceasing AABB standard-setting activities altogether and (b) immediately withdrawing from those few jurisdictions where current law may present a particularly significant risk to the AABB. Fundamental to its decision is the Board's belief that AABB standards and the accreditation of facilities against those standards increases the safety of blood transfusion. The Board opted instead to seek a legislative solution to limit risk in New Jersey and to proceed immediately with a risk analysis of current law in other states. To the extent, however, that a legislative solution is not achieved in New Jersey or that a risk in another jurisdiction cannot be minimized, the Board will again consider the option of withdrawing from AABB's standard-setting and accreditation-related activities.

For the present, the Board also determined that continuation of both standard-setting and accreditation related activities in their current form would not be prudent. Accordingly, the Board requested that the following options for

change to AABB's standard-setting activities be developed.



Any or all of these options may be adopted in October. Members are asked to consider each option carefully and to communicate their comments and concerns to the Board.

### **Option 1—Change the Standard-Setting and/or Accreditation Processes**

Currently, AABB standards are established by a committee of experts in blood collection and transfusion practices. Committee members are chosen from the AABB membership. Non-voting liaisons from relevant government agencies (FDA and CDC) and other private organizations with interests in blood safety are also invited to participate. Standards proposed by the committee are published for comment in publications designed to reach AABB members. Although there is no prohibition on comment from the general public, the current process does not pursue public participation. Among the assertions made by the New Jersey court in finding against the AABB was that the AABB set its standards without input from the public so that decisions benefitted the association and member interest, without due regard for the safety of the public. Implicit in this assertion is the idea that public comment or input during the standard-setting process would have forced or encouraged the AABB to consider broader interests, thereby reducing potential legal risk to the association. The standard-setting process might be

more inclusive if one or more of the following approaches were adopted:

- **Public Representation on the Standards Committee.** AABB could consider expanding the Standards Committee to include participation of individuals representing the public interest either in a voting or non-voting capacity. Clearly, with public participation, any standard established would have the benefit of an expanded review and consideration of concerns related to the public interest that might not otherwise have surfaced. The difficulty associated with this option is its potential for delay. Expanded participation could increase the already cumbersome review process and potentially delay creation of new standards and/or the periodic review of existing standards. Additionally, selecting appropriate public representatives could create further obstacles and possibly fail to account for the interests of a particular group that might later claim to have been improperly excluded.
- **Public Comment on Draft Standards.** Draft standards prepared by the committee could be published for comment by the general public. (Although formal distribution to other professional organizations might lead to more universally accepted standards, it may not address the concerns of the *Snyder* court because the professional organizations selected could still be perceived to have a special self-

interest in setting standards.) This option, in either form, increases the complexity of the process and potentially delays the implementation of important new standards. Moreover, determining what level of publication is appropriate presents further concerns, ie, publication in a professional journal versus publication in the lay press.

- **Adoption of Standards by Inspected Facility.** AABB's current standards are based upon the best medical practices and scientific data, when available. Although efforts are made to harmonize these standards with governmental requirements, AABB standards are independent from these requirements. Similarly, the standards do not represent the most rigorous standards attainable in blood banking and transfusion medicine. Rather, the standards represent "accepted performance guidelines that may be exceeded in practice" ("Introduction," *Standards for Blood Banks and Transfusion Services*, 17th Edition). Accordingly, the "Introduction" to the current edition of *Standards* (as well as the introductions in prior editions) instructs institutional and individual members to make their own decisions as to whether AABB standards are appropriate or whether more rigorous internal requirements should be implemented in their own facility. However, legal counsel for some blood collection and transfusion facilities, including those involved in Mr. Snyder's injury, have defended their clients'



actions on the basis that they effectively surrendered all independent judgment in favor of simple compliance with AABB standards.

To reduce risk to the association, the AABB could require as part of the accreditation process that the facility document that responsible personnel within the institution have made an informed judgment that adoption of AABB standards is appropriate for their institution. The purpose of this formality would be to underscore the intent of the standards and the responsibility of each institution with respect to the adoption of those standards.

This option has the advantage of being relatively simple to implement and helpful in clarifying the role and responsibility of the institution in relying on AABB standards; however, it would not, by itself, eliminate risk to the AABB.

## **Option 2—Change the Basis Under Which Standards are Established**

As noted, AABB standards are independent from governmental requirements and represent "accepted performance guidelines that may be exceeded," rather than the most rigorous standards attainable. Peculiar local conditions or other variables may guide an institution to apply or experiment with additions or alternatives, as some have done. Changing the basis under which standards are established might be achieved by the following approaches.

- **Conform with Government Regulation.** AABB could conform AABB standards to minimal levels consistent with federal requirements (those that are contained in federal regulations) or levels consistent with federal guidelines (those that are recommended or issued as guidelines). Conformance could be sought in all substantive areas or only in those areas that are potentially the source of greatest liability, eg, decisions about which infectious disease tests are to be implemented. This option recognizes the increasingly diminished role of private organizations in establishing public health policy today.

The AABB, however, may not wish to accept a less active role in setting standards for donor testing and screening, particularly if in the future the FDA and/or the Public Health Service become less vigilant.

Moreover, as a private organization without benefit of governmental immunity, there would still exist the potential for lawsuits, on the basis that the AABB failed to set a given standard, having identified itself as a standard-setting organization.

- **Reflect All Member Practices.** AABB could reconfigure AABB standards as a simple statement of current practices of blood centers

and transfusion services, as identified by a survey of the membership. By presenting all variations and embracing none, this option would obviously limit risk to the AABB, but arguably does little to improve collection and transfusion safety. It also provides little or no guidance to members who seek information from the AABB, particularly with respect to emerging problems.

- **Scope of the Standards to Reflect Only the Most General Requirements.** AABB standards could be reconfigured to state only the most general requirements, so that AABB liability for recommending or failing to recommend specific requirements would not be at issue. For example, rather than requiring performance of specific tests for infectious diseases, the relevant standard might require only that infectious disease testing that ensures the safety of blood transfusion be accomplished.



### Option 3—Structure/Substance

Changes to the basis (and corresponding scope and substance) of the standards obviously could be accomplished with revisions to each standard on a case-by-case basis. An alternative structure for *Standards* makes some or all of the suggested changes in scope and substance easier to accomplish, while providing closer alignment with the quality program concept and its systems approach to blood banking operations.

■ **Realignment of Standards to a Systems Approach as Method of Reorganizing Standards to Achieve Flexibility in Establishing Varying Levels of Specificity in standards.** Changing the structure of AABB's standards to realign them with the requirements of the quality program concept would enable the AABB to establish standards in a uniform manner with differing levels of specificity. Standards could correspond with the quality systems necessary to operate blood centers and transfusion facilities in the safest possible manner while permitting the AABB to establish different levels of specificity within each standard based on its potential risk to the association. This approach has the added advantage of being compatible with the ISO 9000 structure.

■ **The quality system identifies the organizational structure, responsibilities, procedures, processes and resources needed to implement quality management.** The quality system is made up of critical control points (CCPs), which are the major/critical processes within a system that must be performed correctly to ensure quality, and corresponding key procedural elements (KPEs) that make up each CCP. The CCPs of a quality system include organizational issues, personnel testing, supplier qualification, process control, documentation/record review, label control, incident/error/accident control, internal assessment and process improvement.

■ **Using this approach, requirements in each standard could range from very broad statements, which require that a system be in place to ensure the proper functioning of a CCP of an operational system, to more specific statements describing the exact methodology by which a specific test is to be performed.** In areas with significant risk, eg, infectious disease testing as identified in *AABB v Snyder*, the requirements contained in the applicable standards would be limited to the broader requirement to have a system in place to accomplish the regulated function in accordance with appropriate regulations or guidelines. The specificity of each standard would be based, in part, on the level of risk associated with the underlying function.

The following example serves to illustrate this approach.

#### Testing Donor Blood

The blood testing facility shall establish and maintain documented procedures for testing activities to verify that the specified requirements for the blood or blood component are met. The required testing, and the records to be established, shall be detailed in the quality plan or documented procedures.

- E1.000 Determination of ABO Group
- E2.000 Determination of Rh Type
- E3.000 Previous Record
- E4.000, E4.100, E4.200, E4.300 Tests for Detecting Unexpected Antibodies to Red Cell Antigens  
(Above standards are as currently stated in *AABB Standards for Blood Banks and Transfusion Services*, 17th edition)

■ **E5.000 Tests Intended to Prevent Disease Transmission**  
A sample of blood from each donation shall be tested for HBsAg, anti-HBc, anti-HTLV, HIV-1 Ag, anti-HIV-1, anti-HIV-2, anti-HCV and with a serologic test for syphilis in accordance with federal regulations and requirements or such additional testing as state law may require. Whole blood and blood components shall not be used for transfusion unless the results of these tests are negative.

In an emergency, blood may be transfused before completion of the tests, but a notation to the effect that testing is not completed shall appear conspicuously on an attached label or tag. If any test is subsequently reactive, the recipient's physician must be notified.

In accordance with the systems approach, the general statement above establishes that certain basic requirements must be identified and documented in the facility's quality plan or procedures. Where limited risk is associated with underlying specific requirements, such requirements would continue to be reflected in the standard, eg, inclusion of E1.000-E4.000 above. Where significant risk is associated with the underlying requirements, however, the standard would reflect only general guidance, eg, the suggested change to E5.000 above. Additional specifics regarding the types of tests to be performed would be left to government regulation in this case or perhaps some other form of guidance provided by the AABB.



## Board Action

The Board will consider carefully all of these options and any others suggested. A decision as to which of the options to be chosen will be made at a special Board meeting following member discussion at the Annual Meeting. The Board may decide to implement any one, all, or some of the options suggested. *Members are urged to provide written comments to the Board through the AABB National Office or verbal comments through a teleconference, scheduled for September, and the "Ask the Board" session at the AABB Annual Meeting in October. (Please refer to the Annual Meeting final program for details.)* ♦



# AABB Board Reaffirms Standard Setting Role

At a special meeting on Wednesday, October 16, 1996, the Board of Directors of the American Association of Blood Banks (AABB) reaffirmed the AABB's commitment to standard setting as a core activity of the Association. The Board reaffirmed its responsibility to enhance the quality of all aspects of blood services and transfusion practices by setting Standards that are based on good medical practice and available scientific data and that supplement federal regulations and recommendations when necessary.

Specifically, the Board unanimously agreed to the following:

1. That public representatives from significantly affected groups be sought to participate in discussions regarding development of Standards.
2. That draft Standards be distributed for public comment, including comment from key professional associations.
3. That the Standards Committee and the Board review and respond to public comments.
4. That the AABB move Standards toward a quality systems framework that retains an appropriate level of detail consistent with current Standards.
5. That incorporation of management consent by institutional members in the adoption of AABB Standards be explored.

Roger K. Svoboda, President, notes, "These decisions reflect the strong sentiment of the membership that the AABB should not retreat from its role as a voluntary standard setting organization. The Board will continue to review options available to the Association to minimize AABB's liabilities related to its standard setting activities. As we move forward, additional changes will proceed using existing AABB practices to ensure member input."

Svoboda continues, "AABB Standards help provide a safer blood supply in the United States. We will continue to monitor our standard setting process and revise it as necessary to continue that role and still protect our Association."



September 27, 1996

## SPECIAL REPORT

Donor Incentives Discussed at FDA Workshop

The incentives currently used by blood collection organizations to motivate volunteer (non-remunerated) blood donors and the possibility that these incentives may compromise the safety of the blood supply were discussed this week at a workshop co-sponsored by the Food and Drug Association (FDA) and the National Heart, Lung, and Blood Institute on September 25, 1996. Although the acceptability of any particular donor incentive was not decided during this workshop, many interesting issues were raised by meeting attendees including whether there truly are altruistic donors. A central issue was whether or not there are sufficient data to make decisions in this area and whether it is feasible to conduct such studies. But whatever their position on the current adequacy of data, workshop participants agreed that it should be examined in an interdisciplinary fashion to include scientific, socioeconomic and psychological points of view.

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*"Even with data, some decisions are hard, and we can't always hide behind this excuse."*

—Steven Kleinman, MD

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Opening the workshop, Kathryn Zoon, PhD, director of FDA's Center for Biologics Evaluation and Research, called donor incentives "an area of great concern for FDA"

because current donor incentives may compromise blood safety and because of the increased competition for a limited donor base. Dr. Zoon added that she hoped the workshop would be an open discussion of the issues and would help design a study to evaluate this issue.

FDA is focused on three issues, said Jay Epstein, MD, director of Office of Blood Research and Review: whether incentives are necessary to maintain the blood supply; if there are incentives that do and do not affect the safety of the blood supply; and whether there are questions that can only be answered through further study. "This is a charged issue lately due to lots of finger pointing," Dr. Epstein said. Although these issues may be commercial and on the business-side of the industry, FDA is concerned about them because they may affect the safety of the blood supply, he said.

National Blood Policy. In 1972, the US Government began pursuing a set of national policy initiatives for blood that were directed at supply, quality, accessibility and efficiency, explained Michael Dubinsky, deputy director of FDA's Office of Compliance. The quality initiative was described in part

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*"This is a charged issue lately due to lots of finger pointing."*

—Jay Epstein, MD

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in a specific statement: "It is the policy of the US Government to encourage, foster, and support efforts designed to bring into being an all-voluntary blood donation system and to eliminate commercialism in the acquisition of whole blood and blood components for transfusion purposes." Since that time, Mr. Dubinsky said, FDA has grappled with many significant issues in regulating the blood supply to meet the demands of the nation's health care system,

including the issue of post-transfusion hepatitis and donor reclassification labeling requirements of 1978.

Although the ground rules for recruiting donors—regional blood programs without competition—were spelled out in the National Blood Policy, competition is very apparent now, Mr. Dubinsky said. Since the 1990s, donor incentives such as cash payments to blood drive sponsors and cash payments to third parties based on the number of donors at a blood drive have become an area of concern for the FDA, he said.

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Donor Incentives (continued from page nine)

Of the approximately 2,300 error and accident reports received by the Office of Compliance in 1996, Mr. Dubinsky said, 36 percent were associated with post-donation information relating to behavioral questions. The donor incentive "rule is clear and fine", but it may not translate into the days of HIV and increased competition, he said. Noting that another section of the National Blood Policy that addresses the need to educate donors about the need for a safe blood supply, he asked "Has marketing replaced education?"

**Paid Cytapheresis Donors.** Ronald Strauss, MD, medical director of DeGowin Blood Center, University of Iowa College of Medicine explained that in the 25 years they have used paid cytapheresis donors, there has been no detectable decrease in transfusion safety when the donors adhere to a structured system. Under this system, donors must meet all FDA and American Association of Blood Banks (AABB) criteria; have a permanent address and phone; attend an orientation session and sign a written consent form; donate a unit of whole blood first; keep all scheduled appointments (drop-in donations are not allowed); survive repeated donor screening and infectious disease testing; and agree to HLA typing and leukocyte antibody testing.

A DeGowin Blood Center study that compared the percentage of donors deferred for infectious disease for volunteer whole blood donors (N=917) and paid cytapheresis donors (N=1,240) revealed that 0.98 percent of volunteer donors were deferred for a history of infectious disease and 6.95 percent were deferred for infectious disease testing, Dr. Strauss reported. In contrast, 0.48 percent of paid cytapheresis donors were deferred for a positive history and 3.70 percent were deferred for positive testing. "Paid cytapheresis donors are not less safe than volunteer donors at our center," Dr. Strauss asserted, and in some instances, data appear to suggest the superior safety of apheresis components, most likely due to the repetitive testing and screening of apheresis donors, he said.

To monitor donor safety, each year the blood center compares the percentage of whole blood and apheresis platelet units that are discarded because of repeatedly reactive infectious disease screening tests or factors in the medical history pertaining to infectious diseases, Dr. Strauss said. Over the last four years, the percentage of whole blood units discarded consistently is higher than that for apheresis platelet units, he reported, suggesting that the relative safety of units from volunteer and paid donors has been maintained. Dr. Strauss concluded that a scientific approach should be taken for all allogeneic donors, that long-term studies for post-transfusion infection are unreasonable, and that safety should be determined by the available data and reasonable expectations. Any regulations, requirements, or guidelines that may be changed to document and monitor donor safety "must be applied identically to all types of allogeneic donors," he argued.

**Blood Centers and Mental Gymnastics.** The issue of donor incentives has created a dilemma for the blood banking industry, said Thomas Asher, PhD, retired chairman of HemaCare Corporation. If the incentive is too big, blood banks worry that the donor will do anything to obtain the reward and if it is too small, the donor will not donate. The "mental gymnastics" in the blood banking industry to deal with this has been "amazing," he said, adding that "there is nothing like it in the commercial plasma field." Dr. Asher explained that donor recruitment should be a negotiation process with the donor that explains what is expected from the donor and what the donor can expect in return from the collection center. One assumption is that a donor will always want a reward, but it may be material or "ethereal," he said, asking "Is there much difference?" Later, during the panel discussion, Dr. Asher asked "what is wrong with telling the truth" about the donation process and telling donors that "there is nothing in it for you."

James Reilly, president of the American Blood Resources Association said there is an inherent risk in any donation whether or not the donor is paid or a volunteer. The plasma industry has spent more than

(continued on page eleven)



Donor Incentives (continued from page ten)

60 million dollars on voluntary initiatives and new technologies to make the blood supply safer. "We want to make the safest products without regard to donor incentives," he said.

**Donors are the Real Concern.** "The competition that exists and is ever-growing between the blood collecting facilities must not become a situation in which donors feel they are a free source of supply for a business that uses them to gain market advantage," said Jane Mackey, president of Kansas Blood Services, speaking on behalf of AABB. The increasing talk of market shares, margins, consolidations, mergers, a safer blood supply, and new tests "accomplishes little except creating divisiveness between us and resentment from our most important audience—blood donors," she said. "All of the safety measures imaginable are of little value if there are no donors who are willing to roll up a sleeve" and donate, Ms. Mackey said.

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*"Competition . . . between blood collecting facilities must not become a situation in which donors feel they are a free source of supply for a business that uses them to gain market advantage."*

*—Jane Mackey*

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AABB's 1989 edition of *Administrative Guidelines for Blood Banks* defines a voluntary donor as "a person who

meets patients' blood and component needs by donating without receiving compensation or [certain] inducements from the collecting facility, sponsor or other external source." In 1994, AABB issued an association bulletin stating that in the absence of additional data demonstrating the safety of certain practices, the following strategies should be considered to represent compensation/inducements:

- Cash payment or cash equivalent
- Lottery tickets
- Discounts on merchandise
- Valuable merchandise
- Tax deductions
- Reduction in fees for premarital screening tests in association with a blood donation
- Community service credits for parolees
- Alternative sentencing/judicial sentence reduction
- Credits toward raising grades for high school or college students
- Raffle tickets.

AABB could not reach consensus on other donor incentives, Ms. Mackey said, citing blood assurance benefits to the donor or others; cancellation, discount or refund of the blood replacement/deposit fee; free supplemental laboratory screening or diagnostic testing; time off from work unrelated to the time required to donate; and tickets to events. The AABB bulletin also included several questions for blood collecting organizations and their community advisory groups to use in determining whether an incentive may be an inducement.

Despite criticism from AABB members, the position stated in that 1994 bulletin remains AABB's position in 1996, Ms. Mackey said. "AABB encourages an examination of the broader issues of donor motivation and donor examination of the strategies on blood safety and adequacy" and studying effective ways to motivate lowest-risk, committed blood donors, she said. "The real concern is the donor," she said. "It would be a tragedy to ever discover that an incentive motivated an unacceptable donor to give blood, or if the competition for donors through the use of incentives so destabilizes the blood supply that we lose donors."

(continued on page twelve)



Donor Incentives (continued from page eleven)

Toby Simon, MD, president of Blood Systems Foundation and president of the Council of Community Blood Centers (CCBC) said that "CCBC believes that altruistic volunteer blood donations should be perceived as a benefit from both a safety and ethical point of view" and that the "most important incentive for donation should be the ability to save a human life." The Council believes that inappropriate rewards to donate include excessive time off from work that can be converted to cash under employee benefit plans, payment of cash discounts to groups or anyone in exchange for productive donation, and donation as an alternative to judicial sentencing or as a tax deduction. Demands for reduction in the cost of blood by health care institutions related to the number of donors pose another concern, Dr. Simon said. The use of such things as mugs, concert and raffle tickets, and t-shirts should be used judiciously by the blood center but "they should be made available to anyone who presents for donation," he said. There is value in further clarifying the regulations, Dr. Simon said. But he cautioned that any action that would decrease the adequacy of the blood supply could have serious impact and should be coupled with other steps that could improve the adequacy of the blood supply, such as accelerated re-entry schemes, shortened donor interview forms, or a more rapid donor interview for repeat donors.

Agreeing with the industry representatives who had spoken earlier, Barbara Mobley, director of Donor Marketing at American Red Cross, said the underlying concern is how donor incentives affect the safety of the blood supply. Noting that she did not intend to discuss what donor incentives the Red Cross found acceptable or not, she expressed her hope that this would be the first discussion of volunteer donors "according to the CFR [Code of Federal Regulations]." The issue of donor incentives has been grappled with for years, she said, and the issue is filled with "feeling, passion and accusations between blood centers." Although there is no clear definition of what is or is not an incentive that would

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*"[Some recent innovations] push the envelope on what is an acceptable donor incentive."*

*—Barbara Mobley*

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cause an unsafe blood donation, some recent innovations "push the envelope on what is an acceptable donor incentive, Ms. Mobley said. In addition to donor incentives, she said that incentives to motivate sponsor groups when setting up blood drives also needed to be investigated. She suggested that the "credibility and objectivity of the federal government" is needed, and that the Public Health Service should be involved in a study to determine what are acceptable donor incentives. Facts and objective research are needed to determine a definite answer to the question of donor and sponsor incentives. Red Cross will "await research results before applying hard and fast rules," she concluded.

**Donor Motivation.** Jane Piliavin, PhD, professor of Sociology and Women's Studies, University of Wisconsin-Madison, and a member of the Blood Products Advisory Committee, said that pure altruism—where another's interests are more important than your own—is rare. There is a tricky balance between rewarding and rewarding too much, she said. Research has shown that if children are rewarded "up front" for something they find enjoyable, these "controlling rewards" will undermine their intrinsic motivation. If the incentive is offered at the end of the process, she said, it will not undermine the intrinsic value of the process. The best predictor of assuring continued donation from a donor should be coordinated with the donor's sense of self-motivation, Dr. Piliavin said. Blood centers should make the donation process a pleasant experience for the donor by avoiding delays, cutting down on the number of donor history questions, having donor centers conveniently located and having skilled phlebotomists. If the donors are self-motivated, we don't "need to add extrinsic incentives," she said.

"The United States is not self-sufficient when it comes to our blood supply; approximately two percent of the blood supply is imported," asserted Mark Popovsky, MD, acting chief executive officer and

(continued on page thirteen)



Donor Incentives (continued from page twelve)

chief medical officer of the American Red Cross Blood Services in Dedham, Massachusetts. As a result, he said, blood shortages are a frequent and predictable problem. Current challenges in recruiting donors include: corporate down-sizing which results in less people at business blood drives; a longer, more intrusive donation process; an explosion in telemarketing; changes in family demographics with more two wage earner families with less free time; donor loss due to false-positive tests; loss of young donors and an aging population that is not adequately recruited; a transient population; and the persistence of the "infectious risk myth"—ten percent of repeat donors think it is possible to contract an infectious disease through the donation process.

Many of the items given by blood collectors and blood drive sponsors (raffle tickets, discounts on merchandise, event and lottery tickets, and time off from work beyond that needed to donate) as recognition items may serve as a primary motivation for blood donation, Dr. Popovsky said. These activities may have undesirable consequences such as decreased safety of the blood supply, decreased donor altruism (eleven percent of repeat donors believe donors are paid) and decreased public confidence in the blood supply. "The increased competition for donors may confuse the donors themselves and diminish their enthusiasm to donate," he added. In conclusion, Dr. Popovsky called for research to answer these questions and massive efforts to educate donors.

**Corporate Perspective.** Phyllis Gunderson, manager of Employee Programs at Lockheed Martin Missiles and Space (LMMS) in Sunnydale, California explained LMMS management's philosophy that as a "corporate citizen" it was their responsibility to help employees in their volunteer efforts. LMMS supports on-site blood drives, which include a team of three blood centers at once, at the company's expense. In 42 years of sponsoring blood drives, Ms. Gunderson said, LMMS has collected 300,000 units. LMMS pays for the actual time off required to donate, maintains the employee donor re-

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*"It's the pies."*

—Phyllis Gunderson

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records and a consistent blood drive schedule, and provides the publicity for the blood drives. Ms. Gunderson said that 20 percent of the staff donate at least once a year and that this is divided equally between the salaried and union staff. Many of the firms' retirees return for the blood drives. In explaining what works for LMMS in sponsoring blood drives, she said, "it's the pies." Instead of supplying cookies for the donors, LMMS provides pies; the donors enjoy socializing over their piece of pie, she said.

**European Perspective.** Professor W. G. Van Aken, medical director of the Central Laboratory of the Netherlands Red Cross in Amsterdam stated that since the 1980s, the International Society of Blood Transfusion's Code of Ethics has specified that donors be voluntary and non-remunerated; donor health and safety is of constant concern; anonymity of donor and patient should be maintained; there will be no discrimination as to race, nationality or religion; and that the blood collection process is under the responsibility of a physician. Non-paid donors provide an ethical and safety advantage over paid donors, Professor Van Aken said. A non-remunerated donation is an act of altruism and a unique act of living tissue. Commenting on the safety advantage, he said that "whenever new or newly-recognized transfusion-transmitted diseases are identified and tested for, the positive marker rate in the commercial sector exceeds those in the private, not paid sectors."

**HIV Test-Seeking a Concern.** The results of the third phase of a Center for Disease Control and Prevention (CDC) multi-center study of HIV seropositive blood donors revealed that major motivation for donation (61.2 to 77.6 percent) was to help the community, said Steven Kleinman, MD, consultant and transfusion medicine specialist. The study cohort comprised 532 allogeneic donors, 280 (52.5 percent) who admitted to known HIV risk factors at the time of the study interview. Donor incentives

(continued on page fourteen)



Donor Incentives (continued from page thirteen)

received by the study cohort included time off from work (23.7 percent—9.2 percent of the cohort received time off in excess of time needed to donate), gifts (16.4 percent), and gifts in excess of \$5.00 in value (7.3 percent). But fewer individuals stated that these potential incentives were a major or significant motivator for donation (time off, 3.4-8.9 percent; gifts, 2.5-5.7 percent).

"Since 1988, we have been unable to remove motivation to seek HIV testing as a reason to donate blood as indicated by the 14.8 percent of the cohort who identified this as their main motivation," he said. If these data are applied to the expected frequency of HIV infected donors presenting during the seronegative infectious window period (estimated at 1 in 450,000 prior to HIV p24 antigen testing), time off from work may be attracting approximately one HIV infectious donor per 5 million donations, Dr. Kleinman cautioned.

*"Since 1988, we have been unable to remove the motivation to seek HIV testing as a reason to donate blood."*

—Steven Kleinman, MD

**Hemochromatosis and the Blood Supply.** According to Sharon McDonnell, MD of CDC, there are approximately 1.5 million people in the US are affected by iron overload,

primarily due to the genetic disorder of hereditary hemochromatosis. Currently, only 1 to 5 percent of these individuals have been diagnosed. Periodic phlebotomy is used to effectively treat the condition by removing excess iron. The CDC Division of Nutrition has begun activities and plans towards a national program for the prevention and control of this disease, Dr. McDonnell said. This program includes health education, cost-effective screening programs and working with public and private agencies to address the large amount of blood that will be drawn if routine or universal screening is put into practice. The average amount of blood collected in the first phase of "de-ironing" is approximately 43 units per year per person, she said. The maintenance phase of treatment may involve collecting nearly five to ten units of blood per year for the remainder of the patient's life.

**Risk/Benefit Analysis.** Costs associated with therapeutic phlebotomy range from zero to \$250/unit or more and frequently are not covered by insurance, Dr. McDonnell reported. Many physicians therefore advise their patients to donate blood as a means of obtaining free phlebotomy therapy, she said. This raises concerns about the safety of the blood because it encourages donors to be dishonest. Currently, FDA requires special labeling for the use of therapeutic phlebotomy units from hemochromatosis patients and AABB standards prohibit transfusion of these units.

*"No categories of incentives have levels of risk that differ significantly from those of first-time donor or common demographic categories such as males and donors in the 25-44 year age group."*

—Alan Williams, MD

The Retrovirus Epidemiology in Donors Study (REDS) conducted a pilot donor motivation study in the spring of 1995, reported Alan Williams, MD, a Red Cross research scientist. The pilot included questions about blood donation incentives received at the time of last donation, as

well as donors' responses to hypothetical incentives. Responses were received from 64.7 percent of the 12,000 donors surveyed. At the time of last donation, 29.1 percent of the respondents received "token recognition" for donation, 10.4 percent received a "compensatory" incentive and 15.7 percent received a "miscellaneous" incentive, the study found.

"When compared against a deferrable risk estimate of 1.9 percent for the overall group of respondents, both univariate and multivariate analysis showed that donors who reported received blood credit, token recognition, and supplemental medical testing has slightly lower levels of reported risk than all donors."

(continued on page fifteen)



Donor Incentives (continued from page fourteen)

Dr. Williams said. But donors who reported receiving "extra time off from work" or incentives from the "gift" category had marginally higher levels of reported risk (all  $p < .05$ ). "Despite these trends, no categories of incentives have levels of risk that differed significantly from those of first time donor or common demographic categories such as males, and donors in the 25-44 year age group," he said.

In marked contrast, donors who reported use of CUE (confidential unit exclusion), or those who donated to receive the results of HIV testing at their last donation had levels of deferrable risk that were significantly higher than donors who reported receiving incentives and all demographic subgroups. "The availability of CUE procedures and deferral of donors who seek HIV test results appear to be effective risk reduction options for donors who fail to report deferrable risk behavior at the time of donor screening," Dr. Williams said.

William Miller, MD, president of The Blood Center of Southeastern Wisconsin reported on the effect the distribution of free tickets to live rock concerts had on the positive viral disease marker rates in the Dallas-Fort Worth Metroplex. "During the three years that the free tickets were distributed by the radio station that sponsored the blood drives, testing losses, particularly ALT and anti-HBc, rose to three times normal among these young adults, then fell when the concerts were discontinued," Dr. Miller said. Several donors tested positive for HIV-1 when the tickets were distributed; positives dropped to none after they were discontinued. At the same time, the number of donors at the radio station drives decreased, he observed.

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*"The real objective is risk reduction, and there is risk associated with all forms of medical intervention."*

*—Lewellys Barker, MD*

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"Our risk management challenge is to ascertain whether and how we can use donor incentives and other options to achieve a balance between reducing disease risks and maintaining an adequate blood supply at an affordable cost—essentially the objectives of the National Blood Policy of the early 1970s," said Lewellys Barker, MD, a consultant who retired recently from a long career in public health service and transfusion medicine. Dr. Barker offered three strategy options to achieve transfusion transmitted disease risk reduction that could be part of the public health policy-making framework:

- build and strengthen bonds at the local community, county and state level, as well as the national level, between blood transfusion service professions and their counterparts in public health organizations in both the government and the academic/private sector;
- apply incentives to the management of every organization involved in blood donor recruiting and collection to reduce the risks associated with their blood and blood products as far as possible;
- and remove terms such as "safe blood" from our everyday language.

"The real objective is risk reduction," Dr. Barker said, "and there is risk associated with all forms of medical intervention."

During the panel discussion at the end of the day, Dr. Kleinman said he'd heard during the morning sessions that there were no data to illuminate the debate, and then he heard during the afternoon sessions that there was *some* data. Noting that such data are hard to obtain, he recommended studying the information that is available and extrapolating from there. "We have the picture" of the current situation, he said. "We can't continue to say we need more data to make a policy. Even with data, some decisions are hard, and we can't always hide behind this excuse," Dr. Kleinman concluded. □



## Appendix F:

### The Canadian Red Cross Fractionation Corporation

The Canadian Red Cross Fractionation Corporation (FracCo) is a separate, not-for-profit, no share capital corporation, of which The Canadian Red Cross Society is the sole member. It has its own Board of Directors, chief executive officer and staff structure. As the corporation's sole member, the Red Cross is responsible for appointing all the members of FracCo's Board of Directors. Nominees from Red Cross are appointed to ensure adherence to the Fundamental Principles of the Red Cross, protection of the Red Cross image and financial integrity--all of which are included among FracCo's corporate objects. One of these must be a member of the Board of Governors. The others are currently two former Governors and the current Secretary General of the Canadian Red Cross who is also the Chairman of FracCo.

All other members of the Board are independent outside directors with no previous connection to the Red Cross. The Board of Governors of the Canadian Red Cross would be open to considering members of consumer organizations for appointment to the board of FracCo, with the proviso, consistent with corporate law, that they must agree to act in the best interests of the corporation and not as representatives of any special interest group.

A strategic relationship with Bayer Corporation enables FracCo to obtain the benefits of the most up-to-date technology from this acknowledged leader in research and product development in the field of plasma fractionation worldwide. In addition, Bayer will train the staff of the facility and purchase any manufacturing capacity excess to Canadian needs to process its own plasma.

This combination of advantages, along with the expanding plasma collection activities of the Red Cross, should result in FracCo successfully meeting its objective of producing sufficient product of the highest quality and safety standard to satisfy the requirements of the Canadian healthcare system. This product would, of course, be offered to Canadians at a highly competitive price. In essence, Canadians would receive the product at the same price at which it is offered to Bayer, to which Bayer must add its marketing and other related costs, as well as profit. Although there is no guarantee that the CBA would choose FracCo in any open bidding process, the Master Agreement does provide that, as long as it is cost-efficient and cost-effective, the CBA will "use every reasonable effort" to select the Red Cross as the supplier of blood products.<sup>1</sup>

Bayer has the option to purchase any partially manufactured material or finished products surplus to the needs of Canadians at a fair price. Any proceeds from such sales would be re-invested in the Canadian blood program to reduce its cost to the Canadian taxpayer. Plasma donors will be notified in advance that their

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<sup>1</sup> "The Master Agreement," §7.04, p. 4.



gift may be used in this way, although there is no intention to over-collect plasma for this purpose. Where several products are made from the same basic raw material (like refining crude oil) some imbalance will always exist between what is produced and what is required in Canada. Shortfalls have to be covered by imports while surpluses can offset import and other costs.



*CISCO & BLIS, A Comparison of the Functions of  
Two Blood Services Computer Systems*

<i>CISCO</i>	<i>BLIS</i>
<b><i>Donor Management</i></b>	
Donor record management	Record donors
National deferral registry	Local deferrals
Donor recruitment	
Duplicate donor processing	
<b><i>Clinic Management</i></b>	
Clinic scheduling	
Clinic set-up planning	
Remote clinic functions	
<b><i>Laboratory</i></b>	
Link to test devices	Record test results
Lookback/traceback	Limited lookback/traceback
<b><i>Process management</i></b>	
Quality control support	
Equipment maintenance schedule	
Inventory management	
Order processing	







# LEGISLATIVE STRUCTURE:

## BLOOD SHIELD

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# BLOOD SHIELD

## I. INTRODUCTION

The ability to use blood and blood derivatives ("BBD")<sup>1</sup> in medical treatment has been repeatedly characterized as one of the most important advances in medical science. In the vast majority of cases the use of BBD is effective in reducing suffering, morbidity and mortality. In some cases however the use of BBD, although meeting the immediate needs of the recipient, is the effective cause of adverse reactions, infections, or renders the recipient more liable to disease mechanisms.

The risks associated with the use of BBD are varied, change with time,<sup>2</sup> and, although some may be known, others may be unknown. Some of the known risks may be avoidable, others - if the use of BBD is medically mandated - are unavoidable.

It is clear that the operation of one or more of these risks has caused, and, if BBD continues to be used, will continue to cause, physical and economic damage to some recipients and their families.

This paper will address the following issues:

- A. Under what circumstances and by what rationale can an individual, damaged by the use of BBD, seek compensation from supply chain participants.
- B. Whether current Canadian compensation mechanisms are appropriate where BBD is supplied as part of medical treatment.

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<sup>1</sup> The term "derivatives" is chosen over the more usual term "products" as the latter has a legal connotation in product liability law and the former does not.

<sup>2</sup> *Miller, Strict Liability, Negligence and the Standard of Care for Transfusion-Transmitted Disease* (1994) 36 Ariz. L. Rev. 407 lists hepatitis, AIDS, HTLV I and II, Cytomegalovirus whereas Gioia, *Blood Transfusions and the Transmission of Serum Hepatitis: The Need for Statutory Reform* (1975) 24 A.M.U.L. Rev. 367 dealt only with the risk of serum hepatitis. Presumably 1996 articles will refer to Creutzfeldt-Jakob Disease (CJD).



- C. Whether other compensation models might better meet the needs of injured individuals and the societal interests served by the Canadian blood supply system.

This analysis is based on a review of jurisprudence, legislation and publications from some jurisdictions in the United States and elsewhere which have addressed these issues. However, it is not a comprehensive review, and its limitations should be noted. The research for this brief was conducted over time and should not be assumed to represent a current nor comprehensive state of the law.

## II. CANADIAN LIABILITY & COMPENSATION PRINCIPLES

Where a risk from the use of BBD operates to the detriment of an individual "recipient"<sup>3</sup> causing legally recognized damage, the recipient may seek to transfer the cost or economic consequences of such damage to one or more blood supply participants.<sup>4</sup>

A recipient's success in cost transfer i.e. obtaining compensation, is a function of the availability of a judicially recognized legal remedy.<sup>5</sup> The remedies available at any particular point in time are circumscribed by decisional law and legislation. In Canada, the primary remedies currently available are those which arise under the law of negligence and the law of contract.

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<sup>3</sup> The word "recipient" is used to include initial recipient as well as those who are consequentially damaged by the receipt - spouses, children et al.

<sup>4</sup> The word "participants" is used to include all persons and entities who are involved in the ultimate supply to a recipient from donor to final transfuser.

<sup>5</sup> Compensation may be payable under private insurance schemes, workers' compensation etc., however such third party payments are usually not deductible from the cost calculation but are recoverable by rights of subrogation.



### (a) Liability in Tort

The tort of negligence requires, as a threshold, that the claimant demonstrate the existence of a duty of care and a breach of the relevant standard of care. If the risk<sup>6</sup> which operated was unknown, unavoidable, or warned against, or if the supply was effected under circumstances consistent with the applicable standard of care, these factors, individually or cumulatively, will usually constitute a complete defence. In short, in the absence of demonstrable "fault" or "blameworthy conduct" on the part of the supplier, the recipient is obliged to bear the economic consequences of BBD damage.

#### (i) The Duty of Care

The Society has a general common law duty to take reasonable care in its activities so as to avoid foreseeable harm to recipients.

In *Pittman Estate v. Bain*,<sup>7</sup> the general duty was expressed in the following terms:

The CRCS did have a duty to render the blood as safe as it reasonably could for the use of the recipient. If the CRCS knew of a potential risk to the consumer, then it had a duty commensurate with the degree of risk and with the gravity of the potential harm to the recipient, to protect the consumer.

The standard of care against which the Society's activities were measured in *Pittman* was that of "a reasonable blood bank similarly situate".

The obligation to exercise reasonable care applies to all stages of activity and consequently is referable to selection, inspection, testing, design, as well as the provision

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<sup>6</sup> The word "risk" is preferable to "defect" or "impure" as such adjectives merely serve to preordain a legal conclusion.

<sup>7</sup> (1994), 112 D.L.R. (4th) 257 at 319.



of directions or warnings with respect to its use. In *Buchan v. Ortho Pharmaceutical*<sup>8</sup> and in *Pittman* the primary foundation for imposing liability lay in a negligent failure to warn. This duty is an element of the general duty of care.<sup>9</sup> Other readily identifiable elements are the exclusion of inappropriate donors, testing mechanisms, deactivation procedures, labelling, information given to the recipient, and the technical aspects of the transfusion process.

#### (ii) Standards - Common Law

In determining whether conduct is blameworthy, court focus on the reasonableness of the actor's conduct - in this case, the blood supplier. The choice of a particular standard by which to judge conduct is a function of societal standards of fairness and the utility of the endeavour. Clark in *Product Liability*,<sup>10</sup> states:

Traditionally, the standards have been determined by balancing the magnitude of the risk inherent in the conduct at issue against the societal benefits or utility of that conduct.

This balancing process is seldom explicitly recognized by courts but is implicit in the conceptual infrastructure of negligence.

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<sup>8</sup> (1986), 25 D.L.R. (4th) 658.

<sup>9</sup> The following principles provide parameters for the duty to warn:

- the duty is owed to the ultimate recipient and is a continuing one even after the product has been used. It is triggered by knowledge of potential danger
- the duty is to be exercised in an expeditious and timely fashion and although it can be given to a learned intermediary, the duty incorporates an obligation of follow-up
- the warning must be communicated clearly and understandably and calculated to alert the user to the nature, gravity, and extent of the risk.

See *Buchan and Pittman*, *supra*. See also *Lambert et al v. Lastoplex Chemical Company Ltd.* (1972), S.C.R. 569, and *Rivtow Marine Ltd. v. Washington Iron Works* (1974), 40 D.L.R. (2nd) 532.

<sup>10</sup> S. M. Waddams, *Products Liability* 3rd ed. (Toronto: Carswell, 1993) at 20.



In *Pittman* the trial Judge engaged in such a balancing process and stated:<sup>11</sup>

In the case of blood [and presumably all related products], the societal need for the component produces different considerations. This is not a product that should be removed from the market if inherently dangerous. Blood is an essential source of life to many. Although it is a biologic, and therefore, dangerous, the need for the product outweighs the risk. This does not relieve the collector of the blood from the duty to exercise reasonable care, but it perhaps dictates that the collector who does exercise reasonable care, should not be held liable, in the absence of fault on its part, for something that it could not reasonably prevent.

and also stated:

In cases involving commercial products, there are policy considerations in support of liability that is not applicable to a blood bank. While the fact that the CRCS is a non-profit organization does not exculpate it from responsibility for negligence, it should not be held to the standard of care imposed on commercial manufacturers who are in the business for a profit and who pass on to their consumers the expense of their liability.

In *Buchan* the commercial "for profit" manufacturer was found liable for its failure to warn. In *Pittman* a similar liability was imposed upon the "non-profit" Society. Consequently, it does not appear that the non-commercial nature of the Society generated any different standard at all.

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<sup>11</sup> *Supra*, note 7 at 313.



(iii) standards - statutory

The Society, like other manufacturers, is subject to a high degree of regulation at all steps of "supply", from initial collection<sup>12</sup> to final distribution.<sup>13</sup>

Compliance with statutory standards provides no substantial defence, but non-compliance may constitute *prima facie* evidence of negligence. In *Buchan*, the Ontario Court of Appeal concluded that a drug manufacturer's package insert fell short of the common-law duty to warn even though the insert was in compliance with regulations, was approved by a special advisory committee, and had been accepted by the Minister. The Supreme Court of Canada in *R v. Saskatchewan Wheat Pool*<sup>14</sup> stated:

There does seem to be general agreement that the breach of a statutory provision which causes damage to an individual should in some way be pertinent to recovery of compensation for the damage.

The Court considered the English position (existence of the tort of statutory breach) and that of United States (breach of a statute is part of the tort negligence) and resolved the vacillating Canadian position to the principle that, if a statutory breach causes damage, such breach may be evidence of negligence.

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<sup>12</sup> The Drug Directorate Guidelines for Blood Collection and Blood Component Manufacturing, contain specific provisions addressing donor selection, including guidelines for determining donor suitability and education, blood collection, the testing of donor blood, autologous blood donations and the criteria for mobile blood collection operations. See Drugs Directorate Guidelines for Blood Collection and Blood Component Manufacturing, November, 1992, Part 1 "Collection and Testing" pages 3 to 23.

<sup>13</sup> The Drug Directorate Guidelines also provide specific direction regarding the quality assurance and labelling of blood and blood components, including the standards of computer programs for record keeping, and the information to be included on container labels. See Drug Directorate Guidelines for Blood and Blood Component Manufacturing, November, 1992, Part IV, "Quality Assurance and Labelling" pages 49 to 61.

<sup>14</sup> (1983), 143 D.L.R. (3d) 9 at 13.



The practical effect on a plaintiff in a negligence action of failing to establish fault or legal liability caused Osler, J. to state:<sup>15</sup>

I cannot leave this tragic and extremely difficult case without expressing the view, perhaps unbecoming a trial judge, that the normal process of litigation is an utterly inappropriate procedure for dealing with claims of this nature.

In *Davidson v. Connaught Laboratories*<sup>16</sup> Linden, J. stated, in dismissing the plaintiff's negligence claim for a vaccine induced injury:

This is a sad result for the plaintiff and his family but it is one which I am required by the Law to reach ... The law, as it now stands can furnish no compensation to the plaintiff in these circumstances and on this evidence. Perhaps, when it learns about the result on this litigation, the Legislature will see fit to consider looking into this question of compensation for people who suffer rare allergic reactions to drugs through the fault of nobody.

## **(b) Liability in Contract**

### **(i) General**

The legal distinctions between a claim for a product related injury based on contract and that based on tort remain important in Canadian law. Clark in *Product Liability* states:

The historical distinctiveness between contract and tort is evidenced by the separate tests for defectiveness which they employ. In a product liability context, contractual remedies usually arise from breach of Section 14 of The Sale of Goods Act 1979. The test here is whether or not the product was 'of merchantable quality' or 'fit for its purpose', both of which are interpreted in terms of consumer expectations, which can be ascertained from the terms of the bargain. In negligence, liability is predicated upon breach of a duty of care. The case [in negligence] is centred upon the conduct of the producer, rather than the condition of his product; societal interests, rather than consumers' expectations, are paramount.<sup>17</sup>

<sup>15</sup> *Rothwell et al v. Raes* (1988), 66 O.R. (2d) 449 at 449.

<sup>16</sup> (1980), 14 C.C.L.T. 251 at 280.

<sup>17</sup> Clark, A. M. *Products Liability* (London: Sweet & Maxwell, 1989) at pages 27-28.



The parties to a contract providing for the sale of goods have generally had the right to include express terms as to the nature and quality of the product being transferred in the transaction. Subject to such express terms the common law has been prepared to imply terms so as to give the contract efficacy and to provide for the presumed reasonable expectations of the purchaser as to the nature and quality of the product being purchased. The main warranty is that the goods are reasonably fit for the purposes for which they are sold and, where the particular purposes of the purchaser are either known or imputed to be known to the vendor, that the goods are suitable for those purposes. Upon breach of such a warranty by the vendor, given the presence of privity and consideration, the vendor will be strictly liable (as opposed to absolutely liable) for damages flowing from such breach. Proof of "fault" or "knowledge" in the tortious sense is not an essential element for recovery. Strict liability for breach of contractual warranty shifts the Court's focus of analysis from the actions of the supplier to the nature of the goods themselves. Liability is not based on what the supplier did or did not do, but on the qualities of the goods.

The three essential requirements for the imposition of such strict liability are that goods were sold, they were not as warranted and that the breach of warranty caused damage.

The common law provinces and the territories have given statutory force to the implied warranties via the enactment of a uniform *Sale of Goods Act* [Section II(b)(ii), *infra*].



Two provinces (Saskatchewan and New Brunswick) have enacted legislation to modify the doctrinal and definitional restrictions inherent in *The Sale of Goods Act* through the enactment of "consumer product legislation". Quebec has modified its civil code through specific consumer protection legislation [Section II(b)(iii), *infra*].

Even if a particular contract falls outside the purview of such statutes strict liability may still be imposed upon the vendor by the application of common law principles of implied warranty. [Section II(b)(iv), *infra*]

## (ii) The Sale of Goods Act

This *Act* is only applicable to contracts of sale of "goods" for money consideration and the warranties given under the *Act* are only enforceable by and against one who is party or privy to the contract.

Rodgers, in "The Canadian Blood Delivery System: Liability for Blood Related Injuries,"<sup>18</sup> postulated the following:

Actions for damages for injuries due to blood products in Canada require proof of negligence. The rules of manufacturer's liability differ from those identified by the AMERICAN RESTATEMENT. Therefore, there is little to be gained by framing an action in manufacturer's liability rather than negligence. Canadian liability rules do, however, raise interesting questions about the possibility of an action for breach of provincial Sale of Goods Acts and the warranties therein. The *Food and Drugs Act* defines the term 'sale' as it applies to a drug governed under that Act as including distribution whether or not for consideration. It is unlikely however that reliance on the non-consideration aspect of this definition and the definition from the federal Act could be used to supplement the provincial definition so as to allow access to the strict liability of *The Sale of Goods Act* for breach of the warranties of fitness for purpose and merchantability.<sup>19</sup>

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S. Rodgers *The Canadian Blood Delivery System: Liability for Blood Related Injuries* (1989), 21 Ottawa L. Rev. 311.

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*Ibid* at p. 338.



In *Pittman*, the hospital/patient transaction was held not to be a *Sale of Goods Act* contract as there was no money consideration. The Trial Judge further concluded that the definition of "sale" contained in the *Food and Drug Act* did not assist as that *Act* was not directed to the nature of the contract, and did not abrogate from the definition of "sale" in the provincial *Sale of Goods Act*.

(iii) Consumer Protection Legislation

Some provinces, notably Saskatchewan, New Brunswick and Quebec, have enacted legislation modifying the law of sale of goods in consumer transactions. Although not uniform, these statutes generally eliminate the need for vertical privity so as to enable direct action against a manufacturer, extend a cause of action to "users" and members of the purchaser's family unit, widen the concept of sale of goods to incorporate supply of goods as part of a mixed contract of goods and services, and extend contractual consideration to matters other than money.

In Saskatchewan, for example, *The Consumer Products Warranties Act*<sup>20</sup> has eliminated the sale/service dichotomy by bringing under the *Act* as a "sale", the supply of consumer products as part of an overall contract of services. The *Act* eliminates the need for contractual privity in certain cases by extending remedies to "subsequent owners" and "users". Money consideration in the initial "sale" is not required but some form of exchange (barter, extinguishment of claim) remains necessary. The *Act* requires that the product be



purchased from a "retail seller" who is defined as one who sells consumer products in the ordinary course of that seller's business.

The New Brunswick legislation<sup>21</sup> is similar in scope to the Saskatchewan *Act*. Both statutes extend liability beyond the retail seller, to "manufacturers" in Saskatchewan, and to "suppliers" in the case of New Brunswick. Both statutes disallow any exclusions of the statutory warranties.

In Quebec, the *Consumer Protection Act*<sup>22</sup> applies to contracts for goods and services and extends a consumer's remedies to "subsequent purchasers", although not to users. Consumers have direct recourse against manufacturers for latent defects unless the consumer could have discovered the defect by ordinary examination. The *Act* also provides that the manufacturer "shall not plead that he was unaware of the defect".<sup>23</sup>

In other provinces, such as Ontario, Nova Scotia and Manitoba,<sup>24</sup> and in the Northwest Territories and the Yukon,<sup>25</sup> statutes or ordinances dealing with warranties and liability provide that statutory warranties apply to retail or consumer sales, but the legislation does not eliminate privity and does not, except in the case of Manitoba, broaden the concept of sale.<sup>26</sup> Accordingly, in the Territories, and in provinces other than

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21 Consumer Product and Warranty Liability Act, S.N.B. 1978, c. C-18.1.

22 R.S.Q. 1977, c. P-40.1.

23 See s. 53.

24 Consumer Protection Act, R.S.O. 1990, c. C.31; Consumer Protection Act, R.S.N.S. 1989, c. 92; The Consumer Protection Act, R.S.M. 1987, c. C200.

25 Consumer Protection Act, R.S.N.W.T. 1988, c. C-17; Consumers' Protection Act, R.S.Y.T. 1986, c. 31.

26 The Manitoba *Act* defines "sale" to include transactions where whole or part of the price is paid or satisfied by the exchange of other property.



Saskatchewan, New Brunswick and Quebec, potential liability under consumer protection legislation is similar or identical to that under the *Sale of Goods Act*.

(iv) The Effect of Establishing A Contractual Chain

The relevance of the presence or absence of such a contractual linkage in the transfer of liability lies in the concept of strict liability. The principle of strict liability is central to actions for breach of warranty, but currently has no role in Canadian product liability actions based in tort.

In *Pittman* the Court concluded that in the particular circumstances of the case there was no implied warranty, as a term of a hospital/patient contract, that the blood would be free from disease. The Court went on to consider whether the product was unavoidably unsafe, and discussed the interests of the health care system, the effect of a finding of liability upon health care personnel, and the non-availability of alternatives to society's obvious need for the product.

Such policy considerations do not usually arise in traditional strict liability theory arising from breach of warranty. The true nature of the contractual warranty action is that, if given goods that are "defective" or supplied in breach of warranty, then liability is imposed for all defects, including latent defects and those which would not have been detected even by the application of all skill and judgment. In short, the risk/utility analysis performed by a Court to determine the reasonableness of the conduct of the manufacturer/vendor in a negligence action has traditionally had no place in a contractual action. If the requisite warranty is found to be breached the liability of the supplier is said



to be "strict" in the sense that liability will be imposed despite the fact that all reasonable care was taken, that all professional standards were met or that the defect was unknown, undetectable or unavoidable.<sup>27</sup>

In short, if the law of contractual warranties were to apply, upon demonstrating a breach of a contractual promise which caused injury, the plaintiff will generally succeed, but in the absence of a contract the plaintiff will fail on that ground, i.e. in the absence of negligence.

Those suffering physical or financial damage as a result of the use of BBD under existing Canadian liability rules, will only be entitled to receive compensation from the supplier at fault (in the form of negligence) or for breach of warranty (in the course of contractual performance).

As BBD is rarely supplied under a contract of sale the "strict liability" remedy inherent in such a contract will not be available to form a basis for an award of compensation in Canada.

As BBD induced injury frequently arises without objective fault, actions in negligence will frequently fail to provide a compensation mechanism.

#### (v) Non-Sale Contracts

In *Pittman*, at page 351, the Court noted an important distinction between the U.S. position and the Anglo/Canadian position on the sale/service dichotomy. The trial

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<sup>27</sup> *Frost v. The Aylesbury Dairy Company Ltd.* (1905), 1 K.B. 608.



Judge noted:

In the U.S., if a contract is one for 'sale' within the meaning of the state legislation, then statutory warranties will apply. If a contract is predominantly one for 'service', no warranties apply. ...

Unlike the English and Canadian authorities, the U.S. cases do not seem to consider implying common law warranties to material in a hybrid contract that provides both services and material.

The inflexible and apparently absolute division between contracts for sale and contracts for service in the U.S. does not, however, leave the purchaser without a remedy. In the U.S., a purchaser who is unable to establish a pure contract for sale against the retailer, can still succeed in an action against the manufacturer of the product on strict tort liability.

Canada, on the other hand, has not accepted the U.S. strict products liability approach, and the Canadian purchaser, to succeed against the manufacturer, must establish negligence. Canada and the U.S. have taken different paths.

As the English and Canadian cases imply common law warranties into contracts of mixed services and materials, I will apply their guidance, and cannot follow *Perlmutter*.

At pages 352-53 the trial Judge concluded:

In the absence of strict product liability in Canadian Law, it is often difficult to succeed against a manufacturer given the difficulties in establishing negligence. An equitable result is better achieved by implying the common law warranty of fitness to the material used in the contract for service and material.

The Court in *Pittman* used a variety of rationales to refuse to find an implied warranty in the circumstances of the case before it. However the Court clearly rejected the approach taken by the U.S. Court in the *Perlmutter*<sup>28</sup> case, and concluded that common law warranties could be implied into contracts of mixed services and materials.

### **(c) Strict Liability For Products**

Waddams in *Products Liability* (3d edition) 1993, Carswell, states at page



109:

These examples of implied warranties come from various and apparently isolated areas of the law. My submission is that they can usefully be subsumed within a general principle, namely, that one supplying goods for business purposes is strictly liable for consequential damages caused by their defects.

... It would go further than Anglo Canadian Courts have so far gone by reaching also to suppliers of goods in the absence of any kind of contract and, for example, by gift ... providing that such transactions were in the course of the suppliers business.

Waddams had already stated at page 70:

The next step in the development of the law, I would suggest, is already taken in most American jurisdictions, namely, the open recognition of strict liability in tort, independent of contractual restrictions.

In *Neuzen v. Kom*<sup>29</sup> the Supreme Court of Canada left to another day the issue as to whether strict liability in tort was available as a remedy in Canada.

Rodgers in *The Canadian Blood Delivery System: Liability for Blood Related Injuries* noted:

In the absence of a viable theory of strict liability, injury caused in the absence of negligence will be borne by the victim him or herself.<sup>30</sup>

The question is whether this strict liability, either arising from mere fact of supply as advocated by Waddams, or arising by virtue of a contractual supply with requisite terms, provides a reasonable, fair or rational mechanism if it serves to shift injury costs from the innocent injured user to a BBD supplier who has not been shown to be at fault.

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<sup>29</sup> *Ter Neuzen v. Kom*[1995] 3 S.C.R. 374 at p. 2.

<sup>30</sup> (1989), 21 Ottawa L.R. 311 at 339.



### III. EXEMPTION FROM STRICT LIABILITY - THE UNITED STATES

#### (a) Introduction

The legislatures of forty-nine states<sup>31</sup> have enacted statutory provisions to modify common-law<sup>32</sup> and statutory<sup>33</sup> remedies which otherwise might have been available to recipients injured through the use of BBD. The statutes in effect remove the application of strict liability in its contractual or tortious guises. The statutes leave preserved the remedy in negligence. Any variances in the remedies specifically barred by the statutes are largely a function of the theories of liability in currency at the time of a particular enactment and those subsequent legislative amendments deemed necessary as a result of judicial interpretation and application of the statute. New Jersey<sup>34</sup> does not have a specific statute nor does the District of Columbia.<sup>35</sup> Both states achieve a similar result, i.e. the non-applicability of strict liability for BBD damage, by court decisions based on the application of the comment k. exception to the 1965 Restatement (2d) Tort definition of strict product liability in tort.<sup>36</sup>

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<sup>31</sup> Miller 1994, *supra* note 2 at p. 489 lists 48 states but missed Vermont which passed a statute in 1990 (c. 46).

<sup>32</sup> For example *Greenman v. Yuba Power Products* (*infra*).

<sup>33</sup> For example the statutory warranties contained in the Uniform Commercial Code.

<sup>34</sup> *Brody v. Overlook Hospital* (1974) 317 A. 2d 392 blood is unavoidably unsafe and therefore not unreasonably dangerous.

<sup>35</sup> *Kozup v. Georgetown Univ.* (1988) 851 f.2d 437

<sup>36</sup> See discussion on Comment "k", *infra*



## (b) Legislative Development

### (i) Sale

Early statutes reflected the majority decision in *Perlmutter*<sup>37</sup> and simply provided that the procurement, distribution or use of blood or blood products was the rendition of a service and not a sale. For example Delaware provides:

The implied warranties of merchantability and fitness shall not be applicable to a contract for the sale of human blood, blood plasma or other human tissue or organs from a blood bank or reservoir of such other tissues or organs. Such blood, blood plasma or tissue or organs shall not for the purposes of this Article be considered commodities or goods subject to sale or barter, but shall be considered as medical services.<sup>2</sup>

In many states specific legislation was not seen necessary as courts almost invariably followed *Perlmutter*.

### (ii) Warranty

The *Perlmutter* decision however did not specifically address the issue of whether warranties might also be implied in a contract for services.<sup>38</sup> Second generation statutes reflected not only the *Perlmutter* sales/service distinction, but also negated the applicability of any implied warranties.<sup>39</sup> For example Georgia provides:

The injection, transfusion, or other transfer of human whole blood, blood plasma, blood products, or blood derivatives and the transplanting or other transfer of any tissue, bones, or organs into or onto the human body shall

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<sup>37</sup> See Millar (*supra*, at note 2) at p. 483:

In *Perlmutter*, the New York Court of Appeals held that providing blood is a service rather than a sale and, therefore, that a suit based on a warranty theory could not be brought for hepatitis caused by a transfusion. The court reasoned that a patient goes to a hospital to receive treatment, not to buy drugs, blood or bandages. The drugs, blood, bandages and other things provided by a hospital are part of the treatment the patient is seeking. Blood transfusion is therefore a service and not a sale.

<sup>38</sup> *Shepard v. Alexanian Bros. Hospital* (1973) 33 Cal. 3d 606 p. 635.

<sup>39</sup> See Russell, *Products and the Professional: The Sale & Service Hybrid*, 24 The Hastings Law Journal 111



not be considered a sale of any commodity, goods, property, or product subject to sale or barter but, instead, shall be considered as the rendition of medical services. No implied warranties of any kind or description shall be applicable thereto and no person, firm, or corporation participating in such services shall be liable for damages unless negligence is proven.

States enacting such legislation had clearly removed all contractual claims, leaving injured recipients with the fault based remedy of an action in negligence.

### (c) Strict Liability In Tort

The doctrine of strict liability in tort was first enunciated in *Greenman v. Yuba Power Products* (1963), 377 P. 2d 897. Under this theory a manufacturer could be strictly liable in tort when its marketed article contains a defect that caused injury. This doctrine was subsequently reflected in Section 402A by the American Law Institute in its 1965 Restatement (2d) Tort.

Section 402A reads:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if:
  - (a) the seller is engaged in the business of selling such a product, and
  - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
  - (a) the seller has exercised all possible care in the preparation and sale of his product, and
  - (b) the user or consumer has not bought the product



from or entered into any contractual relation with the seller.

Comment k. reads:

k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidably high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even purity of the ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended by a known but apparently reasonable risk. [Emphasis added]

In the 1967 decision *Community Blood Bank Inc. v. Russell*,<sup>40</sup> the Supreme Court of Florida declined to follow *Perlmutter*<sup>41</sup> and concluded that the blood bank/patient transaction was unquestionably a sale. In 1970 the Appellate Court of Illinois in *Cunningham v. MacNeil Memorial Hospital*<sup>42</sup> concluded that as the hospital/patient transaction in question it was a "sale" (following *Community*), the doctrine of strict liability in tort as set out in 402A of the Restatement was applicable but that a comment k defense

<sup>40</sup> (1967) 196 So. 2d 115.

<sup>41</sup> *Perlmutter* involved a hospital/patient transaction.

<sup>42</sup> *Cunningham v. MacNeal M. Hospital* (1970) 266 N. E. 2D 897



was not available as blood containing hepatitis virus was unreasonably dangerous. Of *Cunningham* it has been stated:

Given the candor of its discussion of the sale-service question, the *Cunningham* opinion might naturally have proceeded to a straightforward appraisal of the chief policy considerations underlying the imposition of strict tort liability on blood producers. Instead, the court employed the kind of highly semantic analysis which it had just rejected as "unrealistic" in connection with the sale-service determination. The opinion was weakened by a highly artificial discussion of whether the presence of hepatitis was a "defect" rendering blood "unreasonably dangerous" as contemplated by the *Suvada* decision and the *Restatement*.<sup>43</sup>

In direct response to the Community Blood Bank decision, Florida enacted legislation to declaring BBD supply a service:<sup>44</sup>

The procurement, processing, storage, distribution, or use of whole blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing the same, or any of them, into the human body for any purpose whatsoever is declared to be the rendering of a service by any person participating therein and does not constitute a sale, whether or not any consideration given therefor; and the implied warranties of merchantability and fitness for particular purpose are not applicable as to a defect that cannot be detected or removed by a reasonable use of scientific procedures or techniques.

Illinois, in turn, legislatively reversed *Cunningham*.<sup>45</sup>

Other states followed suit so as to negate the *Cunningham* approach. The degree to which a particular state has felt obliged to enact or amend its legislation depended upon the treatment accorded the spirit of its legislation. For example, some state courts interpreted the legislation narrowly.

Louisiana had a sales/service - no implied warranty statute, however, in *De*

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<sup>43</sup> Comment: *Strict Liability - Cunningham v. MacNeal* (1971) 66 N.W.U. L. Rev. 80 at page 86.

<sup>44</sup> Fla. Stat. Ann s. 672-316 (5) (West Supp. 1991)

<sup>45</sup> Ill. Ann. Stat. Ch. 111 1/2, s. 5101-3 (Smith-Hurd 1988)



*Battista v. Argonaut - Southwest Insurance Co.*<sup>46</sup> the court concluded that the existing "contractual" statutory wording did not extend to protect the blood supplier from strict liability in tort. Louisiana amended its statute to specifically exclude strict liability. The statute now provides:

The screening, procurement, processing, distribution, transfusion, or medical use of human blood and blood components of any kind and the transplantation or medical use of any human organ, human tissue, or approved animal tissue by physicians, dentists, hospitals, hospital blood banks, and nonprofit community blood banks is declared to be, for all purposes whatsoever, the rendition of a medical service by each and every physician, dentist, hospital, hospital blood bank, and nonprofit community blood bank participating therein, and shall not be construed to be and is declared not to be a sale. Strict liability and warranties of any kind without negligence shall not be applicable to the aforementioned who provide these medical services.<sup>47</sup>

In contrast in *Shepard v. Alexian Bros. Hospital Inc.*<sup>48</sup> the California Court of Appeal concluded that the characterization of blood supply as a service in its section 1606<sup>49</sup> excluded theories of liability based on either warranty or strict liability in tort. In *Hyland Therapeutics v. Gallagher* the Court of Appeal stated of the scope of section 1606:

It should be borne in mind that section 1606 does not immunize Miles and Hyland from liability. Rather, its effect is to require that those who make tort

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<sup>46</sup> *DeBattista v. Argonaut S. W. Ins.*, (1981) 403 SO. 2D 1130

<sup>47</sup> Section 2797 of the Civil Code was also amended to read:

Strict liability or liability of any kind without negligence shall not be applicable to physicians, dentists, hospitals, hospital blood banks, or nonprofit community blood banks in the screening, processing, transfusion, or medical use of human blood and blood components of any kind and the transplantation or medical use of any human organ, human tissue, or approved animal tissue which results in transmission of viral diseases or any infectious agent undetectable by appropriate medical and scientific laboratory tests.

<sup>48</sup> (1973) 33 Cal. 3d 606

<sup>49</sup> Section 1606 provided:

The procurement, processing, distribution, or use of whole blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing the same, or any of them, into the human body shall be construed to be, and is declared to be, for all purposes whatsoever, the rendition of a service by each and every person, firm, or corporation participating therein, and shall not be construed to be, and is declared not to be, a sale of such whole blood, plasma, blood products, or blood derivatives, for any purpose or purposes whatsoever.



claims on the basis of alleged blood-product defects bear the burden of showing that the blood-product manufacturer was either negligently or intentionally at fault<sup>50</sup> This relatively modest restriction upon the theories available to plaintiffs such as these is rationally related to a legitimate state purpose.

### (i) The Legislative Policy

Six states<sup>51</sup> include a policy statement in their respective legislation. Typical of these is that of North Dakota which reads:

**43-17-40. Limitation of liability - Legislative intent.** No physician, surgeon, hospital, blood bank, tissue bank, or other person or entity who donates, obtains, prepares, transplants, injects, transfuses, or otherwise transfers, or who assists or participates in obtaining, preparing, transplanting, injecting, transfusing, or transferring any tissue, organ, blood, or component thereof from one or more human beings, living or dead, to another human being, may be liable as the result of any such activity, save and except that each such person or entity remains liable for his or its own negligence or willful misconduct only.

The availability of scientific knowledge, skills, and materials for the transplantation, injection, transfusion, or transfer of human tissue, organs, blood, and components thereof is important to the health and welfare of the people of this state. The imposition of legal liability without fault upon the persons and organizations engaged in such scientific procedures inhibits the exercise of sound medical judgment and restricts the availability of important scientific knowledge, skills, and materials. It is therefore the public policy of this state to promote the health and welfare of the people by limiting the legal liability arising out of such scientific procedures to instances of negligence or willful misconduct.

### (ii) Judicial Policy

In the absence of such legislation courts have determined that fundamental public policy required denial of a strict liability remedy.

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<sup>50</sup> It is this burden that is removed in strict liability i.e. whether there was a duty of care and whether it was breached

<sup>51</sup> Arkansas, Colorado, Illinois, Nebraska, North Dakota, Texas



The District of Columbia Court of Appeals<sup>52</sup> refused "to apply traditional notions of sales law ..." as:

Treating blood transfusions as an incidental service performed by hospitals comports with reality, and with the policies underlying merchantability liability. Although theoretically a seller's inability to discover defects in the goods he sells is not relevant to a warranty cause of action, we cannot ignore the difficulty of detecting hepatitis in blood given the current state of medical knowledge. To characterize as a sale the supplying of blood would mean that the hospital, no matter how careful, would be held responsible, virtually as an insurer, if the patient were harmed as a result of impure blood. After balancing the safety of the individual with the interests of the hospital (in light of the absence of an adequate test to determine the presence of hepatitis in the blood) and the public interest in assuring the ready availability of blood for medical treatments, we are reluctant to extend ss 2-314 merchantability liability to a nonsale transaction by analogy or by characterizing the transaction as a sale.<sup>53</sup>

Public policy may be such as to render strict liability wholly inapplicable:

In sum, considering the public health implications of blood collection and distribution and the non-profit status of that segment of the industry involved in *Brody*, we were there convinced that it would be inimical to the public interest to call upon the non-profit blood bank and those in its distributive chain to warrant a blood product whose safety was beyond their power to ensure. So here. In 1984, no matter how diligent and aggressive BCBC might have been in donor screening and laboratory testing, it would nevertheless necessarily have supplied some AIDS-contaminated blood. The unfortunate recipient of that blood would be in no different legal or equitable position than the plaintiff in *Brody*, nor would the blood bank. In short, product protection for the patient and legal protection for the blood bank remains the same -- that is, that the blood bank is obliged to do everything it reasonably can do to ensure safety, but it cannot be responsible for what is not within its capacity to control. This rationale of *Brody* was forcefully reiterated by the Supreme Court in *Feldman v. Lederle Laboratories*, 97 N.J. 429, 442, 479 A.2d 374 (1984), the Court there holding that:

When the essential nature of the transaction involves a service rather than a product, public policy may dictate, in view of the status of the provider, that the general welfare is served better by inapplicability of the strict liability doctrine. Further, when the provider is a nonprofit institution that supplies a product and that product is vital to the public health, the doctrine may

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<sup>52</sup> *Fisher v. Sibley* (1979) 403 A.2D 1130

<sup>53</sup> *Supra*, p. 132.



similarly be inapplicable. The common thread that runs through these cases is that in each of those situations there is a strong public policy rooted in the general welfare that justifies imposing responsibility only on the basis of a want of due care (negligence) rather than on the basis of a defective product (strict liability).<sup>54</sup> [Emphasis added]

In like vein, the Supreme Court of Minnesota commented upon the lack of realism inherent in assertions of implied warranties in BBD supply:

We find it difficult to give literal application of principles of law designed to impose strict accountability in commercial transactions to a voluntary and charitable activity which serves a humane and public health purpose. The activities involved in the transfusion of whole blood, a component of the living body, from one human being to another may be characterized as sui generis in that the sequence of events involve acts common to legal concepts of both a sale and a service. Moreover, it seems to us that under the facts in the case before us it would be unrealistic to hold that there is an implied warranty as to qualities of fitness of human blood on which no medical or scientific information can be acquired and in respect to which plaintiffs' physician has the same information, knowledge, and experience as the supplier.<sup>55</sup>

Some claimants have unsuccessfully tried to circumvent sales/service type legislation by asserting a "distinct" claim for strict liability in tort. The judicial response has been to reject the submission not only on the obvious ground that for strict liability in tort one needs a product but on the more intuitive grounds of public policy. In *Juneau*<sup>56</sup> it was stated:

The question must become what is "unreasonably dangerous". Plaintiffs seemingly contend that the blood was obviously unreasonably dangerous because Mrs. Juneau became ill. This cannot be the test. Reasonableness must be determined in light of the need for blood transfusions compared to the likelihood of contracting hepatitis from the transfusions. Blood is vital in surgical procedures. Patients would often die without it. Although it is true

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<sup>54</sup> *Snyder v. Mekhjian et al* (1990) 582 A. 2D 307 at p. 31

<sup>55</sup> *Balkowitsch v. M.W.M. Bld. Bank* (1965) 402 P 2D 585 at p. 811.

<sup>56</sup> *Juneau v. Interstate Blood Bank* (1976) 333 S. 2D 354 at 358



that the possibility of contracting hepatitis does exist in any transfusion, the great need for these transfusions vastly outweighs the possible risks. Added to this consideration is the fact that the latest of techniques are applied to minimize the risk. With this balancing process in mind, this Court holds that blood, after being screened and tested in accordance with the accepted guidelines, cannot and should not be considered to be unreasonably dangerous to normal use. Courts in other jurisdictions have also faced these same arguments and have reached the same conclusions.

In *St. Luke's*<sup>57</sup> the court held:

In our view, the reasoning of the majority of case law leads us to the conclusion that public policy did not require the imposition of liability without fault on hospitals on the basis of either strict liability or breach of warranty.

Similar policy considerations have been applied where the constitutionality of the legislation has been challenged.

- *Hill*<sup>58</sup>

In the case of *Glass v. Ingalls Memorial Hospital* (1975), 32 Ill. App. 3d 237, 336 N. E.2d 495, on facts similar to those at bar the court held specifically the blood legislation did not violate the constitutional prohibition against special legislation. In that case the court noted the imposition of legal liability without fault would have a chilling effect on the exercise of sound medical judgment and would restrict the availability of important knowledge, skill and materials. That finding was based on the unavailability of a test to discover the presence of serum hepatitis in blood or other human organs. The absence of such a test has been cited by the courts of many other states as a justification for their refusal to impose strict tort liability on the distribution of blood.

- *McAllister*<sup>59</sup>

The rationale for excluding blood transfers from the general products liability law is aptly set out in *Heirs of Fruge v. Blood Services*, 506 F.2d 841,

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<sup>57</sup> *St. Luke's Hospital v. Schmaltz* (1975) 534 P. 2D 781

<sup>58</sup> *Hill v. Jackson Park Hospital* (1976) 349 N.E. 2D 541 at p. 543.

<sup>59</sup> *McAllister v. Am Nat. Red Cross* (1977) 240 S.E. 2D 247 at p.249.



(Louisiana law). "Six years ago, the Louisiana legislature — like many others amended its laws to extinguish all causes of action except negligence against blood banks and hospitals supplying whole blood and its components. The reason for the unusual action was simple, and apparently cogent to the legislature: the obvious and overwhelming need for blood and blood products to be used in transfusions and in surgery was barely met by available supplies, and suppliers were threatened by crippling legal liability for a very small but according to the majority of medical authorities — hard to avoid risk that the blood carried undetectable viral hepatitis. If competent and carefully operated blood banks were to survive, the state legislature believed, they required legislative protection."

- *Miles Lab*<sup>60</sup>

It is our view there is a legitimate state interest in manufactured blood products. We concur in the perception that "legislatures have determined that the production and use of human blood *and its derivatives* for therapeutic purposes should be encouraged; and for this purpose those who provide these products, and who are themselves free from fault, should not be required to bear the economic loss which might otherwise be imposed under the rules of strict liability which are applicable to sellers of commercial products generally." (*Cramer v. Queen of Angels Hosp.*, *supra*, 62 Cal. App. 3d 812, 816, 133 Cal. Rptr. 339 (emphasis added).) It should be borne in mind that section 1606 does not immunize Miles and Hyland from liability. Rather, its effect is to require that those who make tort claims on the basis of alleged blood-product defects bear the burden of showing that the blood-product manufacturer was either negligently or intentionally at fault. This relatively modest restriction upon the theories available to plaintiffs such as these is rationally related to a legitimate state purpose.

- *Oklahoma Blood Institute*<sup>61</sup>

We recognize the provision of an adequate blood and organ supply for transfusion and transplantation as a matter of overriding public concern, and we hold that the grant of immunity to those within the transaction of supplying blood for transfusion bears a reasonable relation to the public interest in the maintenance of an adequate blood supply for transfusion needs. Section 2151 is neither arbitrary nor capricious in attaining this object, and amounts to a constitutional exercise of the authority vested in the Oklahoma Legislature in the interest of the welfare of the citizens of this state to insure an adequate blood and organ supply. We therefore reject Appellants' constitutional challenges.

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<sup>60</sup> *Miles Lab. V. Sup. Court* 175 Cal. App 3D 287

<sup>61</sup> *Goss v. Oklahoma Blood Institute* (1990) 856 P. 2D 998 at p. 1004.



State courts have seen the legislative purpose as self-evident:

- *Garvey*<sup>62</sup>

The public policy represented by these statutes is not difficult to discern; blood transfusions are essential in the medical area and there are not now, and realistically there may never be, tests which can guarantee with absolute certainty that the donated blood is uncontaminated with certain viruses.<sup>63</sup>

(iii) Statutory Provisions

The following generalizations may be made with respect to the U.S. legislation:

- Forty-nine states have passed legislation so as to prevent principles of strict liability in either contract or tort being used as the foundation of a claim for BBD injury;
- Of these forty-nine states, forty-eight render the use of the word "product" in its commercial market sense inappropriate by two main devices:
  - (a) declaring blood *et al* to be the rendition of a service.

Alabama<sup>64</sup> provides:

... is declared for all purposes to be the rendition of a service by every person participating therein and whether any remuneration is paid therefor is declared not to be a sale of such whole blood, plasma, blood products, blood derivatives, or other human tissues.

- (b) specifying that blood is not a commodity.

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<sup>62</sup> *Garvey v. St. Elizabeth Hospital* (1985) 697 P. 2D 248 at p. 249.

<sup>63</sup> Or ones yet unknown or yet to mutate into a new form.

<sup>64</sup> See list of Blood Shield Statutes, attached as Appendix "A"



Alaska<sup>65</sup> provides:

The blood, blood plasma, tissue, or organs may not, for the purposes of this chapter, be considered commodities subject to sale or barter, but shall be considered medical services.

- Although as a "non-product" BBD should not be amenable to either contractual or Section 402A strict liability the remedy of "strict liability" has been specifically excluded by nine states. Of that nine, five join with seventeen others to specifically remove all remedies but those arising in negligence;
- fifteen states specifically preserve a cause of action for "wilful misconduct", this is invariably connected with a specific reference to the preservation of negligence as a remedy.
- Some statutes provide a description of the applicable standard of care:

Virginia provides:<sup>66</sup>

32.1-297. Action for implied warranty in connection with transfer of blood or human tissue. — No action for implied warranty shall lie for the procurement, processing, distribution or use of whole blood, plasma, blood products, blood derivatives and other human tissue such as corneas, bones, or organs for the purpose of injecting, transfusing or transplanting any of them into the human body except where any defects or impurities in the said whole blood, plasma, blood products, blood derivatives and other human tissue such as corneas, bones, or organs are detectable by the use of established medical and technological procedures employed pursuant to the standards of local medical practice. (Code 1950, ss 32-364.2; 1968, c. 81; 1979, c. 711.)

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<sup>65</sup> See list of Blood Shield Statutes, attached as Appendix "A"

<sup>66</sup> *Ibid.*







# PROTECTION OF BLOOD DONOR CONFIDENTIALITY

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## **Protection of Blood Donor Confidentiality**

### **Introduction**

This brief outlines the competing interests involved in blood donor confidentiality issues, then canvasses the existing common law and legislative framework both in Canada and in other countries. With this foundation, possible legislative alternatives for Canada are presented for consideration by the Commission of Inquiry on the Blood System in Canada.

This review is based upon a survey of jurisprudence, legislation and publications from some jurisdictions in the United States and elsewhere which have addressed these issues. However, it is not a comprehensive review of all case law and legislation, so its limitations should be noted. The research for this brief was conducted over time and should not be assumed to represent a current nor comprehensive state of the law.

### **Importance of protecting blood donor confidentiality**

The objectives served by protecting blood donor confidentiality in the context of a blood donor system which depends solely upon altruism as the incentive for donation include:

- (a) the maintenance of an adequate supply of blood by minimizing disincentives to donation by individuals who meet the necessary health screening criteria; and
- (b) the maintenance of a safe supply of blood through provision of protections which encourage donors to respond honestly in the health assessment process.

The Canadian Red Cross Society (the "Red Cross" or "Canadian Red Cross") has sought to protect donor confidentiality in furtherance of these objectives, as have many other blood banks in the United States and elsewhere. Indeed, the jurisprudence in this area suggests a widely held and strong view amongst blood bankers that breaches of blood donor confidentiality have a negative impact on the maintenance of a safe and adequate blood supply.<sup>1</sup>

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<sup>1</sup> For example, in the U.S., case law surrounding the issue of the right to have discovery of donors, blood bankers routinely file affidavit evidence to this effect. For example, see *Doe v. American Red Cross Blood Services*, 125 F.R.D. 646 (U.S. Dist., 1989) and *Sampson v. American Red Cross*, 139 F.R.D. 95 (N.D. Tex. 1991). Similarly,



Further, both the American Red Cross and the Canadian Red Cross have conducted surveys which support this conclusion.

The Canadian Red Cross survey was conducted for internal management and planning purposes, in order to identify areas of importance to Canadian Red Cross blood donors and to identify Canadian Red Cross strengths and weaknesses.<sup>2</sup> The statistical consultant who designed the survey later assessed the results which related to donor confidentiality issues and provided his opinion in affidavit form for use in the early stages of the *Pittman* case.<sup>3</sup> The consultant determined that to a statistically significant extent the Red Cross must show itself as discreet and sensitive to donor confidentiality needs and show itself to be trustworthy at the corporate, individual, staff and volunteer levels. He further determined that to whatever extent the Red Cross violated or seemed to violate these donor needs, donors' esteem for the Red Cross would be lessened as would donor willingness to donate blood. It was concluded that if donor confidentiality needs were not maintained, the supply of donated blood would decline.<sup>4</sup>

The study<sup>5</sup> done by the American Red Cross was specifically intended to address the potential effect of reduced confidentiality on blood donors. The study was conducted in 1992 to address what is described in the report as a "controversial issue" for courts of law and blood

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in the early stages of the *Pittman* case, *infra*, when the issue of donor confidentiality was being addressed, Dr. Herst provided such affidavit evidence.

<sup>2</sup> Delphi Consultation Surveys and Research (International) Ltd. conducted this survey in 1989.

<sup>3</sup> Affidavit of Arthur Gillman sworn in support of motion in the *Pittman* case (September 13, 1991). This survey evidence and related affidavit material was not scrutinized by the court as the issues, as they unfolded in the *Pittman* case, did not require it.

<sup>4</sup> Donors were not directly asked whether a weakening of the CRCS position of confidentiality would affect their willingness to donate. Instead, the conclusions are based upon a correlation between the responses to the questions relating to confidentiality, trust and discretion and the responses to other questions on inducement to donate. However, the consultant concluded that the data obtained indirectly could be considered more reliable than donor responses to direct questioning on this issue.

<sup>5</sup> "Changes in intention to donate blood under a hypothetical condition of reduced confidentiality", *Transfusion*, Vol. 33, No. 8, p. 671 (1993).



collection agencies in the United States regarding whether volunteer blood donors should be assured confidentiality in HIV or AIDS litigation.

As set out in the discussion of this study, it examined donors' intentions regarding four blood donation activities, with and without the guarantee of confidentiality:

- (a) provision of accurate medical and personal history information;
- (b) provision of more detailed personal history information;
- (c) acceptance of additional blood tests; and
- (d) future blood donation.<sup>6</sup>

The results of the American Red Cross survey strongly support the position that reduced confidentiality can have a negative impact on safety. Approximately 50% of those donors surveyed indicated a reduced intent to give accurate information about their personal medical information. In addition, of those donors, about one-half said they would nevertheless return to donate blood. This was found to represent a serious threat to the safety of the blood supply in the regions studied. The study also found a significant decrease in the willingness to provide more detailed information and the willingness to take additional blood tests, if requested, concluding that this would impede post-transfusion investigations of infectious diseases in the donor. Lastly, the study found that reduced confidentiality would directly affect the number of repeat donations.

Privacy concerns of individuals extend well beyond the blood donor context. Although the notion of a common law right to privacy is still in its infancy in Canada, there has been a recognition both in the common law and in legislation of the legitimate interests of individuals in confidentiality of their personal health information.

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<sup>6</sup> *Supra*, 672-3.



Within the context of a doctor/patient relationship, the Supreme Court of Canada has held in *McInerney v. MacDonald*<sup>7</sup> that when a patient disseminates highly personal information to a physician, he or she does so with the legitimate expectation that the information will remain confidential. While physician/patient privilege is not generally recognized in the context of disclosure for purposes of civil litigation, the Supreme Court of Canada's decision in *McInerney v. MacDonald* at least supports the public interest in confidentiality of health information.

The need for confidentiality with regard to highly sensitive information has become particularly clear with AIDS, given the social stigma and other serious potential personal ramifications of disclosure of that type of health information. A somewhat unusual illustration of this arises in a case from Quebec<sup>8</sup> where a newspaper ran a story regarding a teacher with AIDS. The newspaper did not use the name of the teacher, but the teacher was nevertheless identifiable. The resulting publicity surrounding his personal life was found to have a disastrous effect on his morale and appeared to contribute to his rapid deterioration. The teacher sued the paper for damages for mental suffering and exemplary damages resulting from the violation of his right to privacy. The court found that the right to privacy, as guaranteed by section 5 of the *Quebec Charter of Human Rights and Freedoms*, includes the right to anonymity, the right to live one's life without interference and one's right to solitude. The court concluded that the defendants had violated the plaintiff's right to privacy by an unjustified publication of information of a purely personal nature, for essentially commercial purposes.<sup>9</sup>

In summary, there is a substantial public interest in maintaining blood donor confidentiality in connection with the maintenance of a safe and adequate blood supply, which is consistent with principles of individual rights to privacy of sensitive personal health information.

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<sup>7</sup> [1992] 2 S.C.R. 138.

<sup>8</sup> *Jean-Pierre Valiquette v. The Gazette et al.* (1991), 8 C.C.L.T. (2d) 302.

<sup>9</sup> See, however, *Turton v. Buttler et al.* (1987), 42 C.C.L.T. 74 (Alta. Q.B.) where the court concluded that the publication of true facts (which were unrelated to AIDS) by a newspaper could not found an action for damages for nervous shock.



## Competing interests

There are, however, a number of public interests which encroach upon the notion of complete confidentiality of blood donor information. They include:

- (a) disclosure requirements to permit fairness within civil litigation;
- (b) disclosure requirements in connection with public health objectives including the control of the spread of disease, and the provision of counselling and other services to those affected; and
- (c) disclosure in connection with criminal sanctions for those rare cases where individuals, knowing that they are at risk, nevertheless attempt to donate blood.

Any proposal for legislative reform should have regard for the need to balance these interests with the interests which are served by protection of blood donor confidentiality. In addition, any proposal for legislative reform should strike an appropriate balance within the context of section 2(b) of the *Canadian Charter of Rights and Freedoms* which guarantees freedom of expression. For example, a publication ban on the blood donor's name within the context of a civil trial will have to bear Charter scrutiny, as it did in the *Pittman* case.

There is, today, some recognition of the need for confidentiality. However, it varies in both degree and uniformity. The following describes the manner in which these competing interests have been addressed within the above three contexts.



**(a) Donor confidentiality in the context of civil litigation**

Within the context of civil litigation, parties normally have broad rights of discovery both with respect to other parties in the litigation, and to a more limited extent with respect to non-parties. These rights of discovery are important, both as a matter of fairness, and in furtherance of expedient resolution of civil disputes. There is therefore a substantial public interest in permitting parties to have access to blood donor information in litigation relating to transfusion associated infections. However, the courts have been prepared, in varying degrees, to recognize and respond to confidentiality concerns.

In Ontario, these issues were first considered in the case of *Sharpe Estate v. Northwestern General Hospital, et al.*<sup>10</sup> In *Sharpe Estate*, Madam Justice Haley of the Ontario Court (General Division) recognized the important competing interests at stake in determining whether certain Red Cross donor records should be ordered disclosed to the plaintiffs. However, the Court was not convinced that the threat which disclosure posed to the public interest in an adequate blood supply outweighed the public interest in insuring that “legitimate tools [were] available in the search for truth in the trial process”. In ordering disclosure, however, it upheld the decision of Master Sandler which sought to minimize the burden of production and the threat to donor privacy through court-imposed restrictions on use of the information disclosed, including the following:

- (a) the disclosure of the identity of donors was prohibited except to the provincial death-records office in order to determine whether the donors were deceased;
- (b) access to the donor names and other information was limited to plaintiffs’ counsel and any expert or agent retained;
- (c) plaintiffs’ counsel was required to obtain a written undertaking to maintain confidentiality from any expert or agent retained;

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<sup>10</sup> (1991), 76 D.L.R. (4th) 535.



- (d) any document filed with the court which revealed the donors names was to be sealed by the Court; and
- (e) any list of names of the donors was to be destroyed upon final disposition of the action.

Similarly, in *Pittman*<sup>11</sup>, the Court recognized the need to protect confidentiality of donor information while still providing the plaintiffs with the information needed to fairly conduct the litigation. A series of orders were made both in the pre-trial procedures, and during the trial, which provided the following protections to confidentiality within the discovery and trial process:

- (a) throughout the proceeding, the donor was referred to by a pseudonym, "Mr. L";
- (b) all documents produced by the CRCS in connection with the action had removed from them any information which would tend to identify Mr. L;
- (c) information from the donor, as a non-party in the discovery process, was obtained in the first instance by written interrogatories to be replied to in affidavit form;
- (d) when the donor's evidence was videotaped in advance of trial, the evidence (including the transcripts and video tapes) were the subject of a confidentiality order of the Court; and
- (e) a publication ban was made at trial with respect to anything which may have tended to identify the donor.

The Canadian Red Cross has developed a practice of arranging for independent counsel to be available to act for any blood donor who becomes involved in civil litigation in order to protect their confidentiality interests independently from the interests of the Red Cross. As a result,

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<sup>11</sup> *Pittman Estate et al. v. Bain et al.* (1994), 112 D.L.R. (4th) 257 (Ont. Ct. (Gen.Div.)).



arrangements are now generally made on consent to provide for confidentiality consistent with the approach taken in the *Sharpe* and *Pittman* cases, with the blood donor's consent.

In the United States, the courts have taken different approaches with a varying degree of regard for the need for confidentiality. For example, while the American Red Cross survey described above provides evidence of the importance of maintaining blood donor confidentiality, it was not readily accepted within the litigation context. This survey was introduced in evidence on a motion to compel disclosure regarding a blood donor in *Long et al. v. The American Red Cross et al.*<sup>12</sup> While the Court recognized that the U.S. survey was well-grounded scientifically, it questioned whether it provided a strong enough factual foundation for the conclusions it reached. The Court reasoned, in the absence of statistical evidence, that it was equally as likely that infringements on confidentiality would make the blood supply safer by discouraging those at high risk from donating, without a negative impact on low-risk donors who would be “unfazed” by the possibility of disclosure.

The skepticism illustrated by the decision in *Long, supra* should be considered in the context of the court's role in balancing competing interests in civil litigation, discussed above. Indeed, where disclosure of donor information has been ordered, U.S. courts have regularly imposed restrictions on the discovery process in recognition of the donor's interest in privacy and the public interest in protection of a safe and adequate blood supply. These restrictions have included:

- (a) requiring that plaintiffs undertake not to initiate actions against donors;<sup>13</sup>
- (b) limiting disclosure to non-identifying information only;<sup>14</sup>

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<sup>12</sup> 145 F.R.D. 658 (1993 U.S. Dist.).

<sup>13</sup> *Jane Doe, et al. v. University of Cincinnati, et al.*, 42 Ohio App.3d 227 (Ct.App.1988), *Roth v. New York Blood Centre*, 596 N.Y.S.2d 636 (N.Y.Sup.Ct. 1993).

<sup>14</sup> *Belle Bonfils Memorial Blood Centre v. Denver Dist. Court*, 763 P.2d 1003 (Colo 1988), *In Re: Complex Blood Bank Litigation*, No. 908-843 (C.A. Super. Ct., San Francisco County, 1990), *Ray, et al. v. American Red Cross, et al.*, No.90-7942 (D.C. Super. Ct., May 29, 1992), *Coleman v. American Red Cross*, 979 F.2d 1135 (C.A. 1992).



- (c) limiting discovery to a series of written interrogatories;<sup>15</sup>
- (d) subjecting the entire discovery process to court supervision, including submitting questions to the court for review prior to examination;<sup>16</sup>
- (e) requiring that plaintiffs undertake to keep donors' names and addresses confidential;<sup>17</sup>
- (f) limiting discovery to telephone interviews not involving disclosure of donor identity;<sup>18</sup> and
- (g) limiting discovery to anonymous questioning of the donor through use of physical barriers such as screens.<sup>19</sup>

Not all of these restrictions have been the result of the exercise of judicial discretion. Many reflect the application of U.S. legislation and state and federal constitutional rights.<sup>20</sup>

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<sup>15</sup> *Borzillieri v. Am. Nat'l. Red Cross*, 139 F.R.D. 284 (W.D.N.Y. 1991), *Diabo v. Baystate Medical Centre*, 1993 WL 78077 (D. Mass 1993), *Belle Bonfils Memorial, supra*, *In Re: Complex Blood Bank Litigation, supra*, *Ray, supra*.

<sup>16</sup> *Belle Bonfils Memorial, supra*, *In Re: Complex Blood Bank Litigation, supra*, *Ray, supra*, *Long et al. v. American Red Cross et al.*, 145 F.R.D. 658 (Ohio, 1993), *John Jones v. American National Red Cross*, Civil Action No. 88-4510 (GEB), (D.N.J. Mar. 1, 1989).

<sup>17</sup> *Tarrant County Hospital District v. Hughes*, 734 SW 2d 675 (Tex. App. 1987), *Mason v. Regional Medical Centre of Hopkins County*, 121 F.R.D. 300 (W.D. Ky. 1988).

<sup>18</sup> *U.B.S. v. The Second Judicial Court and Jeffrey Clark*, No.20375 (Nev. Sup. Ct., Dec. 20, 1989).

<sup>19</sup> *Stenger et al. v. Lehigh Valley Hospital Centre, et al*, 609 A.2d 796 (Penn. 1992).

<sup>20</sup> *Doe v. University of Cincinnati, supra*, *Hoyle v. ARCS*, 149 F.R.D. 215 (D. Utah 1993), *Doe v. ARCS*, No. 88C-169 (Tenn. Cir. Ct., Aug. 8, 1988), *Irwin Memorial Blood Bank v. Superior Court*, 279 Cal. Rptr. 911 (Cal. Ct. App. 1991), *Rasmussen v. South Florida Blood Serv. Inc.*, 500 So. 2d 533 (Fla. 1987), *Gulf Coast Regional Blood Centre v. Houston*, 745 S.W. 2d 557 (Tex. Ct. App. 1988), *Krygier v. Airweld Inc.*, 520 N.Y.S. 2d 475 (N.Y. Sup. Ct. 1987).



Similarly, in one Australian decision,<sup>21</sup> although the Court determined that donor-related records were not *per se* confidential under health-related confidentiality statutes, it recognized the need to protect donor confidentiality through restricting disclosure by:

- (a) requiring that the plaintiffs undertake not to initiate actions against any donors identified;
- (b) restricting the plaintiffs from approaching the donors or serving them with a subpoena without leave of the court; and
- (c) requiring that the plaintiffs seek leave of the court with respect to their use of the information once obtained.

In summary, the above jurisprudence from Ontario, the U.S. and Australia demonstrates judicial recognition of the need for donor confidentiality in varying degrees. A plaintiff's interest in disclosure has regularly been limited to protect competing public interests through imposition of measures restricting the type of disclosure available and the use to be made of disclosed information. However, while these judicially-imposed measures provide some degree of protection for donor confidentiality, at least in Canada they are likely to be administered in a somewhat *ad hoc* fashion due to a lack of explicit statutory guidelines.

#### **(b) Canadian Health-Related Notification Statutes**

Most Canadian provinces now have health-related notification statutes which impose reporting obligations and require, for example, that all findings of HIV seropositivity be reported with identifiers to public health officials.<sup>22</sup> For example, in Ontario, the *Health Promotion and*

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<sup>21</sup> *Australian Red Cross, et al. v. BC.*, No.5065 of 1990 (Sup.Ct. of Victoria, March 7, 1991).

<sup>22</sup> As of 1989, excepting Quebec, Alberta and British Columbia, all other provinces, and the territories required reporting of HIV-positive test results and AIDS cases, with identifiers; Flanagan, W.F., "Equality Rights for People with AIDS: Mandatory Reporting of HIV Infection and Contact Tracing" (1989) 34 McGill Law Journal 530. Extensive evidence about provincial public health regulation and practices was given during the regional hearings of the Commission of Inquiry on the Blood System in Canada, and will not be reviewed here.



*Protection Act*<sup>23</sup> ("HPPA") contains a number of reporting obligations including an obligation which falls upon the Red Cross, as the operator of a laboratory, to report any positive laboratory finding in respect of HIV.<sup>24</sup> Other reportable diseases which may be identified through the blood donation process include hepatitis and syphilis. Exceptions exist where anonymous test sites are authorized.

The *HPPA* was passed in 1983, following the report of the Commission of Inquiry into the Confidentiality of Health Information (1980)<sup>25</sup>, which noted that there was "(n)o consistent treatment or coherent policy regarding the confidentiality of health information reflected in Ontario legislation". At that time, there were eleven statutes administered by the Ministry of Health which contained provisions relating to the confidentiality of information and provided penalties for the breach thereof.<sup>26</sup> The Commission therefore recommended, among other things, that legislation mandating the reporting of health related information only be enacted if necessary to protect the public health and that any such legislation require that information collected be kept confidential and not be disclosed to any third party unless expressly authorized by the legislation or otherwise required by law. Consistent with this recommendation is section 39 of the *HPPA*, which provides as follows:

39.(1) No person shall disclose to any other person the name of or any other information that will or is likely to identify a person in respect of whom an application, order, certificate or report is made in respect of a communicable disease, a reportable disease, a virulent disease or a reportable event following the administration of an immunizing agent.

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<sup>23</sup> R.S.O. 1990 ch. H.7.

<sup>24</sup> *Ibid*, s.29

<sup>25</sup> The Hon. Mr. Justice Horace Krever, *Report of the Commission of Inquiry into the Confidentiality of Health Information* (Queen's Printer for Ontario, 1980).

<sup>26</sup> *Ibid*, Volume III, p.368.



This confidentiality protection is subject to a number of exceptions, set out in subsection 39(2),<sup>27</sup> which permit disclosure in a number of situations. For example, proceedings under the *Criminal Code* and proceedings “for the purpose of public health administration” are exempted. However, there is not a general exception permitting disclosure where ordered by a court.

There do not appear to be any reported decisions interpreting the scope of the confidentiality protection in section 39. However, its plain language bears the interpretation that the Red Cross is statutorily obliged to keep identification information confidential for any blood donor with respect to whom a report has been made to the Medical Officer of Health. This provides only partial protection for donor confidentiality, given that a report is not made for all blood donors who may become involved in litigation, and because it is limited to identifying information but does not prohibit disclosure of the underlying personal health information.

Without attempting a comprehensive review of Canadian health-related notification legislation, it should be noted that some of these statutes do provide for quasi-criminal liability in relation to breaches of obligations imposed on those with communicable diseases. In several provinces, other than Ontario, it is a regulatory offense for persons knowing that they have a communicable disease to fail to consult a physician or to submit to recommended treatment.<sup>28</sup> In

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<sup>27</sup> 39(2) Subsection (1) does not apply,

- (a) in respect of an application by a medical officer of health to the Ontario Court (Provincial Division) that is heard in public at the request of the person who is the subject of the application;
- (b) where the disclosure is made with the consent of the person in respect of whom the application, order, certificate or report is made;
- (c) where the disclosure is made for the purposes of public health administration;
- (d) in connection with the administration of or a proceeding under this Act, the *Health Disciplines Act*, the *Public Hospitals Act*, the *Health Insurance Act*, the *Canada Health Act* or the *Criminal Code* (Canada), or regulations made thereunder; or
- (e) to prevent the reporting of information under section 72 of the *Child and Family Services Act* in respect of the abuse or the suspected abuse of a child. 1983, c. 10, s.38(2), revised.

<sup>28</sup> Friedman, R., “The Application of Canadian Public Health Law to Aids”. *Health Law in Canada*. pp. 49-61.



Ontario, it is an offense punishable by fine on conviction to knowingly report false information to an inspector, medical officer of health, public health inspector or person carrying out a duty, power or direction under the *HPPA* (ss. 100 and 105), but this does not include supplying false information during the blood donor health screening process.

Mandatory reporting itself can be considered a substantial incursion on blood donor confidentiality. Mandatory reporting generally has been the subject of considerable debate, both before and in the context of testing for AIDS. For example, the Report of the Commission of Inquiry into the Confidentiality of Health Information in 1980 stated:

Mandatory reporting contradicts the underlying principle of the health-care relationship that an individual has a right to the confidentiality of health information about himself or herself, including the right to decide to whom the information may be released.

One justification for the interference with the physician-patient relationship is that the benefit which society derives from having information which assists in the prevention or control of disease and bodily harm outweighs the possible harm to the individual in the form of an invasion of privacy. Another justification given is that because society assumes an economic burden in caring for sick members of society it has a right to require those members to do everything reasonable to keep the cost as low as possible. While the right of confidentiality is not absolute, it should not be abrogated without good cause, particularly when an individual, in order to receive necessary treatment, must disclose sensitive information to a health-care provider.<sup>29</sup>

While the focus of the above Report was on the physician/patient relationship, similar principles arguably should apply where an individual discloses sensitive information either in order

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<sup>29</sup> Volume III, p. 75.



to be tested for AIDS, or in connection with donating blood, regardless of whether a physician/patient relationship exists.

Where notification obligations are imposed, it is important that the obligations of the Red Cross to report positive test results, for example, parallel or exceed the obligations of other testing sites. *It must not be easier to get tested by donating blood than by diagnostic testing regimes, so that individuals seeking testing are not attracted to blood donation.* The Canadian Red Cross Society supports anonymous test sites as a means of providing a more attractive testing site.

### **(c) Canadian Criminal Legislation**

At present, the *Criminal Code* does not include a special offence relating to the transmission of HIV or AIDS. However, Justice Minister Alan Rock announced several months ago that criminal legislation for “knowingly communicating” HIV is under consideration in Canada. Notwithstanding the lack of a specific provision, a number of general sections of the *Criminal Code* have been used to address AIDS related issues. In *R. v. Thornton*<sup>30</sup> an individual was convicted of common nuisance endangering the life, health and safety of the public for having donated blood knowing himself to be HIV-infected. Criminal convictions have also been obtained for the transmission of HIV in the context of sexual conduct under *Criminal Code* sections prohibiting criminal negligence causing bodily harm and common nuisance endangering the life, health and safety of the public. The foregoing provisions, as well as those prohibiting unlawfully causing bodily harm, culpable murder by an unlawful act and criminal negligence causing death may also be applicable to those who knowingly donate HIV-infected blood if such donations result in bodily harm to or the death of transfusion recipients.<sup>31</sup>

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<sup>30</sup> (Aug. 14, 1989), Doc. Ottawa-Carleton 759/89 (Ont. Dist. Ct.); affirmed (1991), 1 O.R. (3d) 480 (C.A.); affirmed, [1993] 2 S.C.R. 445.

<sup>31</sup> *Criminal Code*, s.221, s.222(5)(a) and s.220. Most recently, a Canadian jury convicted a man for “mischief endangering life” for having informed a blood centre that he might send actors to lie to test the screening process. *R. v. Hardy* (1996)



Therefore, in those rare cases where individuals donate blood knowing themselves to be HIV-infected, those individuals already face potential criminal liability under existing sections of the *Criminal Code*. The availability of criminal prosecution serves the public interest in deterring acts dangerous to the public well-being. Thus, while the use of the current provisions, or the enactment of a specific criminal provision for knowingly donating HIV-infected blood, might have a negative impact on overall willingness to donate blood, it may also have a positive impact on the safety of the blood supply by discouraging those at high-risk of infection from donating.

Potential criminal liability for blood donation also gives rise to an issue regarding the nature of any obligation on the Red Cross to report to the authorities. Generally, there is no obligation to report a crime. However, there are some specific statutory provisions creating obligations to prevent harm<sup>32</sup> and there may be an issue of civil liability if in the particular circumstances there is a duty of care.<sup>33</sup>

Given the potential impact of reporting confidential information of this type, any reporting obligations should be expressly delineated by statute, and should be to the public health authorities who could then take such steps as are appropriate. Express statutory provisions regarding reporting will also be required if the confidentiality of blood donor information were protected by statute. One approach to meeting the public interest in deterring dangerous activity while preserving as much

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<sup>32</sup> For example, the *Child and Family Services Act*, R.S.O. 1990, c. C.11, requires any individual who believes on reasonable grounds that a child is or may be in need of protection to report that need to the Children's Aid Society. Another example is found at section 10(1) of the *Coroner's Act*, R.S.O. 1990, c. C.27, which requires a person who has reason to believe that a deceased person has died as a result of: violence, misadventure, negligence, misconduct, malpractice, by unfair means, suddenly and unexpectedly, from disease or sickness for which he or she was not treated by a legally qualified medical practitioner, or under such circumstances as may require investigation, must immediately notify a coroner or police officer of the facts or circumstances relating to that death. Another example is found in the *Quebec Charter of Human Rights and Freedoms* which imposes upon every person the obligation to come to the aid of anyone whose life is in peril through personal assistance or by calling for aid, unless it involves danger to that person or a third party or there is some other valid reason for not providing assistance.

<sup>33</sup> For example, in the recent decision of Madam Justice Lang of the Ontario Court (General Division) in *Schamotta v. Clement*<sup>33</sup> a decision by prison officials not to immediately report the disappearance of an inmate from a correctional facility gave rise to civil liability for substantial damages arising from a vicious physical and sexual assault on the plaintiff who lived in the immediate community.



donor confidentiality as possible would be a provision which expressly states that the Red Cross is under no duty to report to authorities, but is entitled to do so in situations where such disclosure is warranted. Moreover, the provision could protect the Red Cross from civil or criminal liability in relation to disclosure or non-disclosure as long as such decisions are made in good faith.<sup>34</sup>

## **U.S. Legislative Initiatives**

In the U.S., a number of states have provided for more comprehensive confidentiality protection, particularly with respect to AIDS<sup>35</sup>. Thus, certain U.S. statutory provisions expressly provide that at least test results, or more broadly "AIDS or HIV related information", be kept confidential except in certain prescribed circumstances, illustrations of which are set out below. These are statutes of general application and therefore apply to, but are not limited to, blood banks. They therefore serve the general public interest in maintaining the confidentiality of such information, and assist in the blood bank's objectives as well. However, none of the statutes reviewed extend confidentiality to all personal or health information collected from blood donors.<sup>36</sup>

Legislation from Illinois and California illustrate statutory provisions which protect the confidentiality of test results, with identified exceptions. The Illinois *Public Health Communicable Diseases AIDS Confidentiality Act*<sup>37</sup> specifically prohibits blood banks and blood centres, among others, from disclosing or being compelled to disclose the identity of a person who has been tested for the presence of HIV infection or from disclosing or being compelled to disclose the results of

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<sup>34</sup> A similar protection for physicians is provided in s.9(a) of the Illinois *Public Health Act*, 410 I.L.C.S. 305 (1994), which provides that a physician may, but is not required to, disclose to a spouse the HIV-infected status of his or her partner.

<sup>35</sup> see page 17

<sup>36</sup> From a review of the AABB Newsbriefs, it appears that many U.S. states have either introduced or passed legislation dealing specifically with confidentiality issues related to AIDS. That source provided a general characterization of the legislation, without particulars. Attached as Appendix "A" is a list of the bills and legislation referred to in that material. A small collection of U.S. statutory provisions which reflect some of the initiatives in this area were reviewed as well.

<sup>37</sup> 410 ILCS 305 (1994) ( excerpts attached as Appendix "B")



such a test.<sup>38</sup> However, a court that is exercising civil or criminal jurisdiction may compel disclosure of this test-related information only after an *in camera* hearing during which the following criteria must be satisfied:

- (a) the person seeking disclosure must demonstrate a compelling need for the test results which cannot be accommodated by other means, with “compelling need” to be determined by weighing the need for disclosure against the privacy interest of the test subject and the public interest which may be disserved by disclosure which deters blood donation and future HIV related testing;
- (b) the pleadings must substitute a pseudonym for the true name of the test subject and disclosure must be communicated confidentially in documents not filed with the court;
- (c) the subject of the test must have notice and a reasonable opportunity to participate in the proceedings if he or she is not already a party;
- (d) any order for disclosure must include safeguards against unauthorized disclosure, specifying the persons who may have access to the information, the purposes for which the information should be used and appropriate prohibitions on future disclosure; and
- (e) the court record relating to this hearing must be sealed<sup>39</sup>.

In addition, this information may be disclosed without a court order to certain persons, including, among others, the test subject, the test subject’s spouse, various health care facilities and

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<sup>38</sup> *Ibid*, s. 9.

<sup>39</sup> *Ibid*, s. 9(g)



providers (which include blood banks and blood centres) and to any public health department to which any person is required to report such results.<sup>40</sup>

The California *Health and Safety Code*<sup>41</sup> requires that all identifying information relating to HIV test results be kept strictly confidential, except for purposes of testing required to be done by blood banks and reported to public health officials and the reciprocal reporting obligation as between public health officials and blood banks.<sup>42</sup> Any disclosure apart from these exceptions can result in the imposition of civil or criminal penalties.<sup>43</sup>

Legislation from Georgia and New York State illustrates legislative approaches which extend the protection for confidentiality beyond test results to “AIDS confidential information” in Georgia, and “confidential HIV related information” in New York.

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<sup>40</sup> *Ibid*, s. 9

<sup>41</sup> D.C.C.A. (1995)

<sup>42</sup> § 1603.1 and 1603.3.

<sup>43</sup> In *Cal. Health and Safety Code* § 199.20 (1995) (excerpt attached as Appendix “C”), these goals are reflected in legislative provisions which state:

To protect the privacy of individuals who are the subject of blood testing for antibodies to the probable causative agent of acquired immune deficiency syndrome (AIDS) the following shall apply:

Except as provided in Section 1603.1 or 1603.3, as amended by AB 488 of the 1985-86 Regular Session, no person shall be compelled in any state, county, city, or other local civil, criminal, administrative, legislative or other proceedings to identify or provide identifying characteristics which would identify any individual who is the subject of a blood test to detect antibodies to the probable causative agent of AIDS.



The Georgia statute<sup>44</sup> does not explicitly deal with blood banks or blood donors, but it sets out general prohibitions about AIDS-related information which may protect donor confidentiality. Section 47 of the statute prohibits any person or legal entity which receives “AIDS confidential information” under that section or which is responsible for recording, reporting or maintaining such information from intentionally or knowingly disclosing such information or from being compelled by subpoena, court order or other judicial process to disclose such information. “AIDS confidential information” is defined broadly<sup>45</sup> to include identifying information which discloses that a person has been diagnosed with AIDS, has or is being treated for AIDS, has been determined to be HIV-infected, has submitted to an HIV test, has had a positive or negative result from an HIV test, has sought and received counselling regarding AIDS, or has been determined to be a person at risk of being infected with AIDS.

The exceptions to the general prohibition on disclosure are similar to those set out in the above-noted Illinois statute<sup>46</sup>. The Georgia statute also provides a mechanism for court-ordered disclosure of AIDS confidential information. A superior state court may order disclosure of AIDS confidential information to a prosecutor in connection with a criminal offense set out in the same statute, any party to a civil cause of action or any public safety agency where an employee of that agency has come in contact with the bodily fluids of the person about whom AIDS confidential information is known. The criteria to be satisfied in order for a court to make such an order are virtually identical to those noted above in relation to the Illinois statute<sup>47</sup>.

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<sup>44</sup> *Official Code of Georgia Annotated* Title 24 Evidence and Title 31 Health, amended to reflect the declaration by the General Assembly in Ga. L. 1988, p.1799 (excerpts attached as Appendix “D”), §1 that AIDS and HIV pose a grave threat to the health and welfare of the people of the state and that the disease is largely transmitted through sexual contact and intravenous drug use. The General Assembly declared the key components in the fight against AIDS to be education and encouragement of voluntary testing for those at risk of transmission. In addition to education, the Assembly asserted its intention to enact measures in the exercise of state police powers in order to deal with AIDS and HIV infection.

<sup>45</sup> § 31-22-9.1.

<sup>46</sup> § 24-9-47.

<sup>47</sup> § 24-9-47(s) and (t).



The New York *Public Health Law*<sup>48</sup> prohibits any person who is providing a health service (which includes clinical laboratory testing) from disclosing or being compelled to disclose “confidential HIV related information”<sup>49</sup>, again subject to certain exceptions. The term “confidential HIV related information” is defined broadly<sup>50</sup> to include any information concerning whether an individual has been the subject of an HIV related test, or has HIV infection, HIV related illness or AIDS or which identifies an individual as having one or more of such conditions including information pertaining to that individual's contacts. Again, the exceptions to the prohibition of disclosure are similar to those set out in the above-noted Georgia and Illinois statutes. Further, disclosure which is not in keeping with the statute may result in criminal liability, although the statute expressly protects blood banks from criminal or civil liability for disclosure in specified circumstances.<sup>51</sup>

The New York statute also prohibits all court ordered disclosure of confidential HIV related information except as expressly provided for in the statute and sets out a procedure similar to that used in Illinois through which the court must find a “compelling need” for disclosure.<sup>52</sup>

Many U.S. states have proposed or adopted criminal legislation which deals with the donation of blood knowing that one is HIV-infected. For example, the *Official Code of Georgia Annotated*<sup>53</sup> makes it a felony for HIV-infected persons, after knowing that they are HIV-infected, to donate blood without previously disclosing that fact to the person taking the blood.

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<sup>48</sup> NY CLS *Public Health* (1994) (excerpts attached as Appendix “E”).

<sup>49</sup> § 2782.

<sup>50</sup> § 2780-7.

<sup>51</sup> § 2783-3.

<sup>52</sup> § 2785.

<sup>53</sup> (1994), § 16-5-60 (excerpt attached as Appendix “F”).



Similarly, Federal criminal legislation has been passed in the U.S. creating the following offense:

§ 1118. *Protection against the Human Immunodeficiency Virus*

(a) IN GENERAL.-- Whoever, after testing positive for the Human Immunodeficiency Virus (HIV) and receiving actual notice of that fact, knowingly donates or sells, or knowingly attempts to donate or sell blood, semen, tissue, organs or other bodily fluids for use by another, except as determined necessary for medical research or testing shall be fined or imprisoned in accordance with subsection (c).

(b) TRANSMISSION NOT REQUIRED. -- Transmission of the Human Immunodeficiency Virus does not have to occur for a person to be convicted of a violation of this section.

(c) PENALTY. -- Any person convicted of violating the provisions of subsection (a) shall be subject to a fine of not less than \$10,000 nor more than \$20,000, imprisoned for not less than 1 year nor more than 10 years, or both.

In addition, a federal bill, the Ryan White *Comprehensive AIDS Resources Emergency Act* of 1990, would extend funding for AIDS research only to those states which have criminal legislation which is adequate for the prosecution of those who donate blood knowing they are HIV-infected with the intention of exposing others to such infection.

With respect to criminal legislation, U.S. states enjoy a constitutional advantage over Canadian provinces and territories in that U.S. states share with the federal government the power to pass criminal legislation. Because the power to pass criminal legislation lies with the federal government in Canada, it is not possible to combine in a single set of provincial or territorial legislative amendments both civil and criminal penalties. However, regulatory offenses which impose certain obligations on donors and provide for prosecution of those who fail to comply with those obligations could be set out in provincial and territorial legislation pursuant to provincial constitutional competence in relation to health care.



## Other jurisdictions

An Australian case<sup>54</sup>, refers to the *Health Act, 1958*<sup>55</sup> which deals with the release of general health information and specifically refers to blood donors. Sections 135 and 136 of that *Act* provide as follows:

135. *Liability of donors*

- (1) No civil or criminal proceedings, other than proceedings under section 136, lie against a donor of blood or tissue by reason only of a person having been infected with HIV by the administration to the person of blood given by, or of a blood product derived wholly or partly from blood given by, the donor or by the transplanting of tissue or the use of semen or ova given by the donor.
- (2) Sub-section (1) does not apply in relation to a donor who has been found guilty of an offence against section 136.

136. *False statements*

A donor must not, in a statement referred to in this Division, make a statement that is false in a material particular.

Without having comprehensively reviewed legislation in other countries, this is the only statutory provision noted which provides immunity to blood donors. However, reports in the CCBC newsletter indicate that legislation making it an offence to give false information regarding donors' suitability has also been passed in the State of Queensland<sup>56</sup>.

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<sup>54</sup> *B.C. v. Australian Red Cross Society, et al., supra*

<sup>55</sup> Statutes of Victoria, Act No. 6270/1958, as am.

<sup>56</sup> CCBC newsletters dated November 30, 1984 and January 25, 1985. These amendments to the *Transplant and Anatomy Act* were apparently rushed through in response to cases of transfusion associated AIDS where three infants received transfusions from a unit of blood donated by an individual who, it was subsequently learned, was a homosexual, was a repeat blood donor and had denied being homosexual on several occasions when being screened as a blood donor.



One Scottish case<sup>57</sup> refers to and relies on the *National Health Service (Scotland) Act 1978* which permits the Minister in charge of public health to object to disclosure of general health information on the basis that such disclosure is not in the public interest. While this statute does not refer specifically to blood donors, it was employed in the context of a case involving donor confidentiality. The effect of an objection by the Minister is to require courts to deny disclosure unless the assertion of the Minister is patently unreasonable. This high threshold for judicial review minimizes the evidentiary problems experienced in Canadian and U.S. civil litigation in attempting to statistically link breach of donor confidentiality with an inadequate or less safe blood supply.

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<sup>57</sup> *Re A.B.* (unreported, December 21, 1989) (Scottish Court of Session).



## RECOMMENDATIONS

For the reasons set out above, the Red Cross recommends:

- **That provincial governments enact specific legislation to protect the confidentiality of blood donor information, balancing public interests by providing for specific exceptions to a general requirement of confidentiality. These exceptions should include:**

- (a) **a procedure to permit access to blood donor information in civil litigation, subject to requirements for:**
  - (i) **use of a pseudonym;**
  - (ii) **a hearing on notice to the blood donor prior to any disclosure being ordered, and**
  - (iii) **controlled use of material once disclosed.**

**- and -**

- (b) **disclosure to meet public health needs including reporting and tracing where appropriate, only to the extent necessary to fulfill the stated public health objectives,**

**- and -**

- (c) **disclosure by the blood collection agency to public health authorities to report possible criminal conduct. The blood collection agency should be granted civil immunity for such disclosure, if made in good faith.**

The latter provision concerning "possible criminal conduct" would discourage donors from providing inaccurate health information. It would be expected that serious incidents of abuse of the blood collection system would be rare, and the blood collection agency would exercise discretion by reporting only serious cases. Furthermore, it would be expected that if a



case is reported to public health, its officials could assess and manage the situation as a public health matter, exercising existing powers in public health legislation if necessary. In the most severe cases of intentional abuse, the public health official could have the option of reporting the case as a criminal offense, as a last resort.

- **That provincial governments enact specific legislation to provide statutory immunity for blood donors against both civil and criminal proceedings, except where the blood donor makes a false statement.**

Statutory immunity has been afforded to blood donors in some of the U.S. jurisprudence in connection with judicially imposed terms in civil litigation. Civil immunity, subject to exceptions for criminal conduct, may be of assistance in encouraging blood donors to give accurate information both at the time of donation, and within the context of civil litigation.

- **That governments enact specific legislation to declare it to be an offense to knowingly give any false information at the time of blood donation.**

This type of provision is intended to act as a disincentive to individuals using blood donation for serologic testing purposes and to stress the importance of candour in the blood screening process. This would provide a mechanism to address those rare instances where individuals attempt to abuse the system.

The Canadian Red Cross Society

Dec 6, 1996



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## APPENDIX "A"

### Health-Related Information Legislation

South Carolina (cited in *Doe v. American National Red Cross*, 788 F.Supp. 884 (1992)).

### References to Test Result Notification Bills

Colorado (AABB Newsbriefs Vol.8, No.10, October, 1985, p.10).

Connecticut (AABB Newsbriefs Vol.8, No.10, October, 1985, p.10).

Florida (AABB Newsbriefs Vol.8, No.10, October, 1985, p.10).

Hawaii (AABB Newsbriefs, Vol.9, No.4, April, 1986, p.6).

Indiana (AABB Newsbriefs, Vol.9, No.4, April, 1986, p.6).

Michigan (AABB Newsbriefs, Vol.9, No.4, April, 1986, p.6).

Montana (AABB Newsbriefs Vol.8, No.10, October, 1985, p.10).

Pennsylvania (AABB Newsbriefs, Vol.9, No.4, April, 1986, p.6).

Virginia (AABB Newsbriefs, Vol.13, No.7, August, 1990, p.2).

### References to AIDS Confidentiality Bills

Hawaii (AABB Newsbriefs, Vol.9, No.4, p.5).

Maryland (AABB Newsbriefs, Vol.9, No.4, p.5).

U.S. *AIDS Federal Policy Act* (AABB Newsbriefs Vol.14, No.4, April, 1988, p.4).



Washington (AABB Newsbriefs, Vol.9, No.4, p.5).

**References to Proposed Criminal Law Bills**

Alabama (AABB Newsbriefs Vol.8, No.10, October, 1985, p.9).

Arizona (AABB Newsbriefs Vol.13, No.3, March, 1990, p.3).

California (AABB Newsbriefs Vol.9, No.4, April, 1986, p.5).

Hawaii (AABB Newsbriefs Vol.13, No.2, March, 1990, p.3).

Iowa (AABB Newsbriefs Vol.9, No.4, April, 1986, p.5).

Kansas (AABB Newsbriefs Vol.14, No.6, Jun3 1991).

Kentucky (AABB Newsbriefs Vol.14, No.4, April, 1988, p.4).

Missouri (AABB Newsbriefs Vol.14, No.4, April, 1988, p.4).

New Jersey (AABB Newsbriefs Vol.13, No.2, February, 1990, p.2).

New York A.4878, S.3753 (AABB Newsbriefs Vol.14, No.6, June, 1991).

Ohio (AABB Newsbriefs Vol.15, No.6, June, 1992).

Pennsylvania (AABB Newsbriefs Vol.8, No.10, October, 1985, p.10).

Tennessee (AABB Newsbriefs Vol.9, No.4, April, 1986, p.5).

Texas (AABB Newsbriefs Vol.14, No.6, June, 1991).

U.S. (AABB FaxNet, No.167, October 4, 1994, p.2).

U.S. *AIDS Control Act of 1989* (AABB Newsbriefs Vol.12, No.1, January, 1989).



**APPENDIX "B" - Illinois Test Results Disclosure Statute**

CHAPTER 410. PUBLIC HEALTH  
COMMUNICABLE DISEASES  
AIDS CONFIDENTIALITY ACT  
410 ILCS 305/2 (1994)

§ 410 ILCS 305/2. [Statement of legislative findings]

Sec. 2. The General Assembly finds that:

- (1) The use of tests designed to reveal a condition indicative of Human Immunodeficiency Virus (HIV) infection can be a valuable tool in protecting the public health.
- (2) Despite existing laws, regulations and professional standards which require or promote the informed, voluntary and confidential use of tests designed to reveal HIV infection, many members of the public are deterred from seeking such testing because they misunderstand the nature of the test or fear that test results will be disclosed without their consent.
- (3) The public health will be served by facilitating informed, voluntary and confidential use of tests designed to reveal HIV infection.

**HISTORY:**

Source: P.A. 85-677; 85-679.

§ 410 ILCS 305/3. [Definitions]

Sec. 3. When used in this Act:

- (a) "Department" means the Illinois Department of Public Health.
- (b) "AIDS" means acquired immunodeficiency syndrome.
- (c) "HIV" means the Human Immunodeficiency Virus or any other identified causative agent of AIDS.



(d) "Written informed consent" means an agreement in writing executed by the subject of a test or the subject's legally authorized representative without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion, which entails at least the following:

- (1) a fair explanation of the test, including its purpose, potential uses, limitations and the meaning of its results; and
- (2) a fair explanation of the procedures to be followed, including the voluntary nature of the test, the right to withdraw consent to the testing process at any time, the right to anonymity to the extent provided by law with respect to participation in the test and disclosure of test results, and the right to confidential treatment of information identifying the subject of the test and the results of the test, to the extent provided by law.

(e) "Health facility" means a hospital, nursing home, blood bank, blood center, sperm bank, or other health care institution, including any "health facility" as that term is defined in the Illinois Health Facilities Authority Act [20 ILCS 3705/1 et seq.].

(f) "Health care provider" means any physician, nurse, paramedic, psychologist or other person providing medical, nursing, psychological, or other health care services of any kind.

(g) "Test" or "HIV test" means a test to determine the presence of the antibody or antigen to HIV, or of HIV infection.

(h) "Person" includes any natural person, partnership, association, joint venture, trust, governmental entity, public or private corporation, health facility or other legal entity.

#### § 410 ILCS 305/9. [Confidentiality; exceptions]

Sec. 9. No person may disclose or be compelled to disclose the identity of any person upon whom a test is performed, or the results of such a test in a manner which permits identification of the subject of the test, except to the following persons:

- (a) The subject of the test or the subject's legally authorized representative. A physician may notify the spouse of the test subject, if the test result is positive and has been confirmed by a



Western Blot Assay or more reliable test, provided that the physician has first sought unsuccessfully to persuade the patient to notify the spouse or that, a reasonable time after the patient has agreed to make the notification, the physician has reason to believe that the patient has not provided the notification. This paragraph shall not create a duty or obligation under which a physician must notify the spouse of the test results, nor shall such duty or obligation be implied. No civil liability or criminal sanction under this Act shall be imposed for any disclosure or non-disclosure of a test result to a spouse by a physician acting in good faith under this paragraph. For the purpose of any proceedings, civil or criminal, the good faith of any physician acting under this paragraph shall be presumed.

- (b) Any person designated in a legally effective release of the test results executed by the subject of the test or the subject's legally authorized representative.
- (c) An authorized agent or employee of a health facility or health care provider if the health facility or health care provider itself is authorized to obtain the test results, the agent or employee provides patient care or handles or processes specimens of body fluids or tissues, and the agent or employee has a need to know such information.
- (d) The Department, in accordance with rules for reporting and controlling the spread of disease, as otherwise provided by State law.
- (e) A health facility or health care provider which procures, processes, distributes or uses: (i) a human body part from a deceased person with respect to medical information regarding that person; or (ii) semen provided prior to the effective date of this Act for the purpose of artificial insemination.
- (f) Health facility staff committees for the purposes of conducting program monitoring, program evaluation or service reviews.
- (g) A person allowed access to said record by a court order which is issued in compliance with the following provisions:
  - (i) No court of this State shall issue such order unless the court finds that the person seeking the test results has demonstrated a compelling need for the test results



which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the need for disclosure against the privacy interest of the test subject and the public interest which may be disserved by disclosure which deters blood, organ and semen donation and future HIV related testing.

- (ii) Pleadings pertaining to disclosure of test results shall substitute a pseudonym for the true name of the subject of the test. The disclosure to the parties of the subject's true name shall be communicated confidentially, in documents not filed with the court.
- (iii) Before granting any such order, the court shall provide the individual whose test result is in question with notice and a reasonable opportunity to participate in the proceedings if he or she is not already a party.
- (iv) Court proceedings as to disclosure of test results shall be conducted in camera unless the subject of the test agrees to a hearing in open court or unless the court determines that a public hearing is necessary to the public interest and the proper administration of justice.
- (v) Upon the issuance of an order to disclose test results, the court shall impose appropriate safeguards against unauthorized disclosure, which shall specify the persons who may have access to the information, the purposes for which the information shall be used, and appropriate prohibitions on future disclosure.
- (h) Any health care provider or employee of a health facility, and any fire-fighter or EMT-A, EMT-P, or EMT-I, involved in an accidental direct skin or mucous membrane contact with the blood or bodily fluids of an individual which is of a nature that may transmit HIV, as determined by a physician in his medical judgment.
- (i) Any law enforcement officer, as defined in subsection (c) of Section 7 [410 ILCS 305/7], involved in the line of duty in a direct skin or mucous membrane contact with the blood or bodily fluids of an individual which is of a nature that may transmit HIV, as determined by a physician in his medical judgment.



- (j) A temporary caretaker of a child taken into temporary protective custody by the Department of Children and Family Services pursuant to Section 5 of the Abused and Neglected Child Reporting Act [325 ILCS 5/5], as now or hereafter amended.
- (k) In the case of a minor under 18 years of age whose test result is positive and has been confirmed by a Western Blot Assay or a more reliable test, the health care provider who ordered the test shall make a reasonable effort to notify the minor's parent or legal guardian if, in the professional judgement of the health care provider, notification would be in the best interest of the child and the health care provider has first sought unsuccessfully to persuade the minor to notify the parent or legal guardian or a reasonable time after the minor has agreed to notify the parent or legal guardian, the health care provider has reason to believe that the minor has not made the notification. This subsection shall not create a duty or obligation under which a health care provider must notify the minor's parent or legal guardian of the test results, nor shall a duty or obligation be implied. No civil liability or criminal sanction under this Act shall be imposed for any notification or non-notification of a minor's test result by a health care provider acting in good faith under this subsection. For the purpose of any proceeding, civil or criminal, the good faith of any health care provider acting under this subsection shall be presumed.



## APPENDIX "C" - California Test Results Disclosure Statute

Stats 1985 ch 23 provides:

SECTION 1. The Legislature finds and declares that acquired immune deficiency syndrome is a serious and growing viral-based epidemic in the United States.

The incidence of acquired immune deficiency syndrome (AIDS) caused by blood transfusions is a growing and serious problem and is expected to increase and since a test will soon be available to indicate exposure to the probable causative agent of AIDS, it is crucial that donations of blood be tested for the presence of the antibodies to the probable causative agent of AIDS to safeguard against the possibility of transmitting the disease by transfusion.

The Legislature finds and declares it is a desired goal to discourage individuals in high-risk groups, as defined by the State Department of Health Services, who are expected to be exposed to AIDS, from donating blood in order to safeguard against transmitting the disease by transfusion.

Furthermore, the Legislature declares that it is imperative to delay notification of all persons who test reactive for the antibody test at a blood bank or plasma center for that period of time necessary to discourage members from high-risk groups from visiting a blood donation site.

### HEALTH AND SAFETY CODE

#### DIVISION 1. Administration of Public Health

#### PART 1. STATE DEPARTMENT OF HEALTH SERVICES CHAPTER 1.11. Mandated Blood Testing and Confidentiality to Protect Public Health

Cal Health & Saf Code § 199.20 (1995)

#### § 199.20. Privacy rights of persons subject to AIDS blood tests

To protect the privacy of individuals who are the subject of blood testing for antibodies to the probable causative agent of acquired immune deficiency syndrome (AIDS) the following shall apply:

Except as provided in Section 1603.1 or 1603.3, as amended by AB 488 of the 1985--86 Regular Session, no person shall be compelled in any state, county, city, or other local civil, criminal, administrative, legislative, or other proceedings to identify or provide identifying characteristics which would identify any individual who is the subject of a blood test to detect antibodies to the probable causative agent of AIDS.

Added Stats 1985 ch 22 § 1, effective April 4, 1985.



§ 199.21. Civil and criminal liability for wrongful disclosure of AIDS test results

- (a) Any person who negligently discloses results of an HIV test, as defined in Section 26, to any third party, in a manner which identifies or provides identifying characteristics of the person to whom the test results apply, except pursuant to a written authorization, as described in subdivision (g), or except as provided in Section 1603.1 or 1603.3 or any other statute that expressly provides an exemption to this section, shall be assessed a civil penalty in an amount not to exceed one thousand dollars (\$ 1,000) plus court costs, as determined by the court, which penalty and costs shall be paid to the subject of the test.
- (b) Any person who wilfully discloses the results of an HIV test, as defined in Section 26, to any third party, in a manner which identifies or provides identifying characteristics of the person to whom the test results apply, except pursuant to a written authorization, as described in subdivision (g), or except as provided in Section 1603.1 or 1603.3 or any other statute that expressly provides an exemption to this section, shall be assessed a civil penalty in an amount not less than one thousand dollars (\$ 1,000) and not more than five thousand dollars (\$ 5,000) plus court costs, as determined by the court, which penalty and costs shall be paid to the subject of the test.
- (c) Any person who wilfully or negligently discloses the results of an HIV test, as defined in Section 26, to a third party, in a manner which identifies or provides identifying characteristics of the person to whom the test results apply, except pursuant to a written authorization, as described in subdivision (g), or except as provided in Section 1603.1 or 1603.3 or any other statute that expressly provides an exemption to this section, which results in economic, bodily, or psychological harm to the subject of the test, is guilty of a misdemeanor, punishable by imprisonment in the county jail for a period not to exceed one year or a fine of not to exceed ten thousand dollars (\$ 10,000) or both.
- (d) Any person who commits any act described in subdivision (a) or (b) shall be liable to the subject for all actual damages, including damages for economic, bodily, or psychological harm which is a proximate result of the act.



- (e) Each disclosure made in violation of this chapter is a separate and actionable offense.
- (f) Except as provided in Article 6.9 (commencing with Section 799) of Chapter 1 of Part 2 of the Insurance Code, the results of an HIV test, as defined in Section 26, which identifies or provides identifying characteristics of the person to whom the test results apply, shall not be used in any instance for the determination of insurability or suitability for employment.
- (g) "Written authorization," as used in this section, applies only to the disclosure of test results by a person responsible for the care and treatment of the person subject to the test. Written authorization is required for each separate disclosure of the test results, and shall include to whom the disclosure would be made.
- (h) Nothing in this section limits or expands the right of an injured subject to recover damages under any other applicable law. Nothing in this section shall impose civil liability or criminal sanction for disclosure of the results of tests performed on cadavers to public health authorities or tissue banks.
- (i) Nothing in this section imposes liability or criminal sanction for disclosure of an HIV test, as defined in Section 26, in accordance with any reporting requirement for a diagnosed case of AIDS by the state department or the Centers for Disease Control under the United States Public Health Service.
- (j) The state department may require blood banks and plasma centers to submit monthly reports summarizing statistical data concerning the results of tests to detect the presence of viral hepatitis and HIV. This statistical summary shall not include the identity of individual donors or identifying characteristics which would identify individual donors.
- (k) "Disclosed," as used in this section, means to disclose, release, transfer, disseminate, or otherwise communicate all or any part of any record orally, in writing, or by electronic means to any person or entity.
- (l) When the results of an HIV test, as defined in Section 26, are included in the medical record of the patient who is the subject of the test, the inclusion is not a disclosure for purposes of this section.



Amended Stats 1991 ch 963 § 2 (AB 1281).

§ 1603.1. Required tests and reports for AIDS and viral hepatitis

- (a) Except as provided in this subdivision, no blood or blood components shall be used in vivo for humans in this state, unless the blood or blood components have been tested and found nonreactive for HIV or the blood or blood components are used for research or vaccination programs pursuant to an informed consent.

Additional exceptions to the requirement of this subdivision are as follows:

- (1) Frozen red blood cells of a rare type, as determined by the blood bank or plasma center, collected prior to the effective date of this paragraph, for which no specimen is available.
  - (2) Inventories of blood and blood components collected prior to 60 days after the effective date of this paragraph or the date of licensing of a test by the Federal Drug Administration to determine exposure to the antibodies to the probable causative agent of AIDS, whichever is later.
  - (3) Blood or blood products released for transfusion in emergency circumstances, as determined by the state department.
  - (4) Blood used for autologous purposes.
- (b) Blood banks and plasma centers shall make laboratory tests of all human whole blood and plasma received to detect the presence of viral hepatitis and HIV in the manner specified in Section 1603.3. If the blood bank or plasma center finds the presence of viral hepatitis, or an antigen thereof, in the blood tested, it shall report that finding, the date of the human whole blood donation, the name, address, and social security number of the person who donated the blood, and the name and address of the blood bank which received the human whole blood from the person and any additional information required by the department, to the department and the county health officer within 72 hours of the



confirmation of the presence of viral hepatitis, or an antigen thereof, in the blood tested.

- (c) As soon as practicable following diagnosis, a physician shall report to the department and the county health officer the name, date of birth, address, and social security number of all carriers of viral hepatitis under his or her treatment, the type of viral hepatitis contracted if known, and any additional information required by the department and shall report immediately all transfusion-associated hepatitis and transfusion-associated AIDS cases to the county health officer for investigation.
- (d) As soon as practicable following hospitalization, a hospital shall report to the department and to the county health officer the name, date of birth, address, and social security number of all confirmed cases of AIDS carriers, as determined by a person responsible for the care and treatment of a person with AIDS, and all carriers of viral hepatitis hospitalized for treatment of viral hepatitis or AIDS, the name of the hospital, the date of hospitalization, the type of viral hepatitis contracted if known, and any additional information required by the department and shall report immediately all transfusion-associated hepatitis and all confirmed transfusion-associated AIDS cases, as determined by a person responsible for the care and treatment of a person with AIDS, to the county health officer for investigation.
- (e) The county health officer shall investigate all transfusion-associated hepatitis cases and transfusion-associated AIDS cases and shall, if possible, trace the sources of human whole blood which was transfused. The county health officer shall report to the department within 72 hours following an investigation the name, date of birth, address, and social security number of carrier donors, possible carrier donors and carriers of viral hepatitis and any additional information required by the department.
- (f) The department shall compile two times each month a list of carrier donors, possible carrier donors, and carriers of viral hepatitis and persons who test reactive for HIV and shall distribute the list to blood banks and plasma centers two times each month. The list shall include the name, date of birth, address, and social security number of people who are carrier donors, possible carrier donors and carriers of viral hepatitis and persons who test reactive for HIV, and confirmed cases of AIDS, as determined by a person responsible for the care and treatment of a person with AIDS, the



date of the human whole blood donation if applicable, the name and address of the blood bank who received the human whole blood donation if applicable, and any other information which the department deems necessary to protect the public health and safety. This list shall be known as the Donor Deferral Register and shall include names of individuals who are indefinitely deferred from blood donations without identifying the reasons for the deferral. The state department may develop guidelines governing the instances when a person is to be removed from the register. These guidelines may include, but shall not be limited to nor be required to include, death of an identified donor or the licenser by the Federal Food and Drug Administration of a new, confirmatory test for AIDS which would allow the state department to more accurately determine if a person should be kept on the registry due to any threat to the state's blood supply that the prospective donor may represent.

- (g) The department shall, if possible, contact carrier donors to inform them that they may be carriers of viral hepatitis and should not make blood donations, and shall suggest appropriate treatment alternatives. County health or state department officials shall contact all persons who have confirmed cases of AIDS, as determined by a person responsible for the care and treatment of the person with AIDS, to suggest appropriate treatment alternatives and for the purposes of epidemiological studies and follow-up.
- (h) The department may adopt regulations governing the procedures in this section as it deems necessary to protect the public health and safety.
- (i) "Plasma center," as used in this chapter, means any place where the process of plasmapheresis is conducted, as defined in Section 1025 of Title 17 of the California Code of Regulations and includes a place where leukopheresis or platelet pheresis, or both, is conducted.
- (j) "AIDS," as used in this chapter, means acquired immune deficiency syndrome.
- (k) "Blood components," as used in this chapter, means preparations separated from single units of whole blood or prepared for hemapheresis and intended for use as final products for transfusions.



- (l) The department or a county health officer may disclose to a blood bank, on a confidential basis, any information reported pursuant to subdivision (b), (c), or (d). This information shall be used by the blood bank solely to determine whether blood previously transfused may have been donated by a person infected with HIV, in order to implement the blood bank's program to notify a recipient of blood which might have transmitted HIV and which was donated prior to implementation of testing procedures for the presence of antibodies to the probable causative agent of HIV. The blood bank shall not disclose information which would identify a donor to which this subdivision applies and shall destroy information communicated to it as authorized by this subdivision immediately after reviewing its records as necessary to implement this program.

§ 1603.3. Notice to donors of AIDS test; Self-deferral; Notice of reactive result; Disclosure to public health officer

- (a) Prior to a donation of blood or blood components each donor shall be notified in writing of, and shall have signed a written statement confirming the notification of, all of the following:
  - (1) That the blood or blood components shall be tested for evidence of antibodies to the probable causative agent of acquired immune deficiency syndrome.
  - (2) That donors found to have serologic evidence of the antibodies shall be placed on a confidential state-wide Blood Donor Deferral Register without a listing of the reason for being included on the register.
  - (3) That the donor shall be notified of the test results in accordance with the requirements described in subdivision (c).
  - (4) That the donor blood or blood component which is found to have the antibodies shall not be used for transfusion.
  - (5) That blood or blood components shall not be donated for transfusion purposes by a person if the person



has reason to believe that he or she has been exposed to acquired immune deficiency syndrome.

- (6) That the donor is required to complete a health screening questionnaire to assist in the determination as to whether he or she has been exposed to acquired immune deficiency syndrome.
- (b) A blood bank or plasma center shall incorporate voluntary means of self-deferral for donors. The means of self-deferral may include, but are not limited to, a form with checkoff boxes specifying that the blood donated is for research or test purposes only and a telephone call back system for donors to use in order to inform the blood bank that blood donated should not be used for transfusion. The blood bank or plasma center shall inform the donor, in a manner that is understandable to the donor, that the self-deferral process is available and should be used if the donor has reason to believe that he or she is infected with the human immunodeficiency virus. The blood bank or plasma center shall also inform the donor that it is a felony pursuant to Section 1621.5 to donate blood if the donor knows that he or she has a diagnosis of AIDS or knows that he or she has tested reactive to the etiologic agent of AIDS or to antibodies to that agent.
- (c) Blood or blood products from any donor initially found to have serologic evidence of antibodies to the probable causative agent of AIDS shall be retested for confirmation. Only if a further test confirms the conclusion of the earlier test shall the donor be notified of a reactive result by the blood bank or plasma center.

The state department shall develop permissive guidelines for blood banks and plasma centers on the method or methods to be used to notify a donor of a test result. Each blood bank or plasma center shall, upon positive confirmation using the best available and reasonable techniques, provide the information to the state department for inclusion in the Donor Deferral Register. Blood banks and plasma centers shall provide the information on donations testing reactive for the antibodies to the probable causative agent of AIDS and carrier donors of viral hepatitis to the department on a single list in the same manner without specification of the reason the donor appears on the list.

- (d) The Blood Donor Deferral Register, as described in subdivision (e) of Section 1603.1, shall include names of individuals who are



deferred from blood donations without identifying the reasons for deferral.

- (e) Each blood bank or plasma center operating in California shall prominently display at each of its collection sites a notice which provides the addresses and phone numbers of sites, within the proximate area of the blood bank or plasma center, where tests provided pursuant to Article 8 (commencing with Section 1630) may be administered without charge.
- (f) The state department may promulgate any additional regulations it deems necessary to enhance the safety of donated blood and plasma. The state department may also promulgate regulations it deems necessary to safeguard the consistency and accuracy of HIV test results by requiring any confirmatory testing the state department deems appropriate for the particular types of HIV tests that have yielded "reactive," "positive," "indeterminate," or other similarly labelled results.
- (g) Notwithstanding any other provision of law, no civil liability or criminal sanction shall be imposed for disclosure of test results to a public health officer when the disclosure is necessary to locate and notify a blood donor of a reactive result if reasonable efforts by the blood bank or plasma center to locate the donor have failed. Upon completion of the public health officer's efforts to locate and notify a blood donor of a reactive result, all records obtained from the blood bank pursuant to this subdivision, or maintained pursuant to this subdivision, including, but not limited to, any individual identifying information or test results, shall be expunged by the public health officer.



APPENDIX "D"- Georgia AIDS-Related Information Statute

TITLE 31. HEALTH  
CHAPTER 22. CLINICAL LABORATORIES  
O.C.G.A. § 31-22-1 (1994)

§ 31-22-1. Definitions

As used in this chapter, the term: ...

(2) "Clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the diagnosis of, recommendation of treatment of, or for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings; the term "clinical laboratory" shall include specimen collection stations and shall include blood banks which provide through their ownership or operation a system for the collection, processing, or storage of human blood and its component parts as well as tissue banks which procure, store, or process human or animal tissues designed to be used for medical purposes in human beings.

(3) "Director" means a person who is responsible for the administration of technical and scientific operation of a clinical laboratory, including supervision of procedures for testing and the reporting of results.

(4) "Person" means any individual, firm, partnership, association, corporation, the state or any municipality or other subdivision thereof, or any other entity whether organized for profit or not.

O.C.G.A. § 31-22-9.1 (1994)

§ 31-22-9.1. HIV tests -- Who may perform test

(a) As used in this Code section, the term:

(1) "AIDS" means Acquired Immunodeficiency Syndrome or AIDS Related Complex within the reporting criteria of the department.



(2) "AIDS confidential information" means information which discloses that a person:

- (A) Has been diagnosed as having AIDS;
- (B) Has been or is being treated for AIDS;
- (C) Has been determined to be infected with HIV;
- (D) Has submitted to an HIV test;
- (E) Has had a positive or negative result from an HIV test;
- (F) Has sought and received counselling regarding AIDS; or
- (G) Has been determined to be a person at risk of being infected with AIDS,

and which permits the identification of that person.

...

(4) "Body fluids" means blood, semen, or vaginal secretions.

(5) "Confirmed positive HIV test" means the results of at least two separate types of HIV tests, both of which indicate the presence of HIV in the substance tested thereby.

(6) "Counselling" means providing the person with information and explanations medically appropriate for that person which may include all or part of the following: accurate information regarding AIDS and HIV; an explanation of behaviors that reduce the risk of transmitting AIDS and HIV; an explanation of the confidentiality of information relating to AIDS diagnoses and HIV tests; an explanation of information regarding both social and medical implications of HIV tests; and disclosure of commonly recognized treatment or treatments for AIDS and HIV. The Department of Human Resources shall develop brochures or other documents which meet the requirements of this paragraph and, upon delivery of such a brochure or document or of another brochure or document approved by the Department of Human Resources to the person and referral of that person to the Department of Human Resources for further information and explanations, counseling shall be deemed to have been provided within the meaning of this paragraph.



(7) "Determined to be infected with HIV" means having a confirmed positive HIV test or having been clinically diagnosed as having AIDS.

(8) "Health care facility" means any:

(A) Institution or medical facility, as defined in Code Section 31-7-1;

(B) Facility for the mentally ill, mentally retarded, or alcoholic or drug dependent persons, as defined in Code Sections 37-3-1, 37-4-1, and 37-7-1, respectively;

(C) Medical, dental, osteopathic, or podiatric clinic;

(D) Hospice, as defined in Code Section 31-7-172;

(E) Clinical laboratory, as defined in Code Section 31-22-1; or

(F) Administrative, clerical, or support personnel of any legal entity specified in subparagraphs (A) through (E) of this paragraph.

(10) "HIV" means any type of Human Immunodeficiency Virus, Human T-Cell Lymphotropic Virus Types III or IV, Lymphadenopathy Associated Virus Types I or II, AIDS Related Virus, or any other identified causative agent of AIDS.

(11) "HIV infected person" means a person who has been determined to be infected with HIV, whether or not that person has AIDS, or who has been clinically diagnosed as having AIDS.

(12) "HIV test" means any antibody, antigen, viral particle, viral culture, or other test to indicate the presence of HIV in the human body, which test has been approved for such purposes by the regulations of the department.

(13) "Institutional care facility" means any:

(A) Health care facility;

(B) Child welfare agency, as defined in Code Section 49-5-12;

(C) Group care facility, as defined in Code Section 49-5-3;



(D) Penal institution; or

(E) Military unit.

(19) "Person" means a natural person.

(20) "Person at risk of being infected with HIV" means any person who may have already come in contact with or who may in the future reasonably be expected to come in contact with the body fluids of an HIV infected person.

(21) "Physician" means any person licensed to practice medicine under Chapter 34 of Title 43.

(22) "Public safety agency" means that governmental unit which directly employs a public safety employee.

(23) "Public safety employee" means an emergency medical technician, fireman, law enforcement officer, or prison guard, as such terms are defined in Code Section 45-9-81, relating to indemnification of such personnel for death or disability.

TITLE 24. EVIDENCE  
CHAPTER 9. WITNESSES GENERALLY  
ARTICLE 2. PRIVILEGE  
PART 2. MEDICAL INFORMATION

O.C.G.A. § 24-9-47 (1994)

§ 24-9-47. Disclosure of AIDS confidential information

(a) Any term used in this Code section and defined in Code Section 31-22-9.1 shall have the meaning provided for such term in Code Section 31-22-9.1.



(b) Except as otherwise provided in this Code section:

(1) No person or legal entity which receives AIDS confidential information pursuant to this Code section or which is responsible for recording, reporting, or maintaining AIDS confidential information shall:

(A) Intentionally or knowingly disclose that information to another person or legal entity; or

(B) Be compelled by subpoena, court order, or other judicial process to disclose that information to another person or legal entity; and

(2) No person or legal entity which receives AIDS confidential information which that person or legal entity knows was disclosed in violation of paragraph (1) of this subsection shall:

(A) Intentionally or knowingly disclose that information to another person or legal entity; or

(B) Be compelled by subpoena, court order, or other judicial process to disclose that information to another person or legal entity.

(c) AIDS confidential information may be disclosed to the person identified by that information or, if that person is a minor or incompetent person, to that person's parent or legal guardian.

(d) AIDS confidential information may be disclosed to any person or legal entity designated to receive that information when that designation is made in writing by the person identified by that information or, if that person is a minor or incompetent person, by that person's parent or legal guardian.

(e) AIDS confidential information may be disclosed to any agency or department of the federal government, this state, or any political subdivision of this state if that information is authorized or required by law to be reported to that agency or department.

(f) The results of an HIV test may be disclosed to the person, or that person's designated representative, who ordered such tests of the body fluids or tissue of another person.

(g) When the patient of a physician has been determined to be infected with HIV and that patient's physician reasonably believes that the spouse or sexual



partner or any child of the patient, spouse, or sexual partner is a person at risk of being infected with HIV by that patient, the physician may disclose to that spouse, sexual partner, or child that the patient has been determined to be infected with HIV, after first attempting to notify the patient that such disclosure is going to be made.

(h)

(1) An administrator of an institution licensed as a hospital by the Department of Human Resources or a physician having a patient who has been determined to be infected with HIV may disclose to the Department of Human Resources:

(A) The name and address of that patient;

(B) That such patient has been determined to be infected with HIV; and

(C) The name and address of any other person whom the disclosing physician or administrator reasonably believes to be a person at risk of being infected with HIV by that patient.

(2) When mandatory and non anonymous reporting of confirmed positive HIV tests to the Department of Human Resources is determined by that department to be reasonably necessary, that department shall establish by regulation a date on and after which such reporting shall be required. On and after the date so established, each health care provider, health care facility, or any other person or legal entity which orders an HIV test for another person shall report to the Department of Human Resources the name and address of any person thereby determined to be infected with HIV. No such report shall be made regarding any confirmed positive HIV test provided at any anonymous HIV test site operated by or on behalf of the Department of Human Resources.

(3) The Department of Human Resources may disclose that a person has been reported, under paragraph (1) or (2) of this subsection, to have been determined to be infected with HIV to the board of health of the county in which that person resides or is located if reasonably necessary to protect the health and safety of that person or other persons who may have come in contact with the body fluids of the HIV infected person. The Department of Human Resources or county board of health to which information is disclosed pursuant to this paragraph or paragraph (1) or (2) of this subsection:



(A) May contact any person named in such disclosure as having been determined to be an HIV infected person for the purpose of counseling that person and requesting therefrom the name of any other person who may be a person at risk of being infected with HIV by that HIV infected person;

(B) May contact any other person reasonably believed to be a person at risk of being infected with HIV by that HIV infected person for the purposes of disclosing that such infected person has been determined to be infected with HIV and counseling such person to submit to an HIV test; and

(C) Shall contact and provide counseling to the spouse of any HIV infected person whose name is thus disclosed if both persons are reasonably likely to have engaged in sexual intercourse or any other act determined by the department likely to have resulted in the transmission of HIV between such persons within the preceding seven years and if that spouse may be located and contacted without undue difficulty.

(i) Any health care provider authorized to order an HIV test may disclose AIDS confidential information regarding a patient thereof if that disclosure is made to a health care provider or health care facility which has provided, is providing, or will provide any health care service to that patient and as a result of such provision of service that health care provider or facility:

(1) Has personnel or patients who may be persons at risk of being infected with HIV by that patient, if that patient is an HIV infected person and such disclosure is reasonably necessary to protect any such personnel or patients from that risk; or

(2) Has a legitimate need for that information in order to provide that health care service to that patient.

(j) A health care provider or any other person or legal entity authorized but not required to disclose AIDS confidential information pursuant to this Code section shall have no duty to make such disclosure and shall not be liable to the patient or any other person or legal entity for failing to make such disclosure. A health care provider or any other person or legal entity which discloses information as authorized or required by this Code section or as authorized or required by law or



rules or regulations made pursuant thereto shall have no civil or criminal liability therefor.

(k) When any person or legal entity is authorized or required by this Code section or any other law to disclose AIDS confidential information to a person at risk of being infected with HIV and that person at risk is a minor or incompetent person, such disclosure may be made to any parent or legal guardian of the minor or incompetent person, to the minor or incompetent person, or to both the minor or incompetent person and any parent or legal guardian thereof.

(l) When an institutional care facility is the site at which a person is at risk of being infected with HIV and as a result of that risk a disclosure of AIDS confidential information to any person at risk at that site is authorized or required under this Code section or any other law, such disclosure may be made to the person at risk or to that institutional care facility's chief administrative or executive officer, or such officer's designee, in which case that officer or designee is authorized to make such disclosure to the person at risk.

(m) When a disclosure of AIDS confidential information is authorized or required by this Code section to be made to a physician, health care provider, or legal entity, that disclosure may be made to employees of that physician, health care provider, or legal entity who have been designated thereby to receive such information on behalf thereof. Those designated employees may thereafter disclose to and provide for the disclosure of that information among such other employees of that physician, health care provider, or legal entity, but such disclosures among those employees are only authorized when reasonably necessary in the ordinary course of business to carry out the purposes for which that disclosure is authorized or required to be made to that physician, health care provider, or legal entity.

(n) Any disclosure of AIDS confidential information authorized or required by this Code section or any other law and any unauthorized disclosure of such information shall in no way destroy the confidential nature of that information except for the purpose for which the authorized or required disclosure is made.

(o) Any person or legal entity which violates subsection (b) of this Code section shall be guilty of a misdemeanor.

(p) Nothing in this Code section or any other law shall be construed to authorize the disclosure of AIDS confidential information if that disclosure is prohibited by federal law, or regulations promulgated thereunder, nor shall anything in this Code section or any other law be construed to prohibit the disclosure of information which would be AIDS confidential information except that such information does not permit the identification of any person.



(q) A public safety agency or district attorney may obtain the results from an HIV test to which the person named in the request has submitted under Code Section 15-11-35.1, 17-10-15, 42-5-52.1, or 42-9-42.1, notwithstanding that the results may be contained in a sealed record.

(r) Any person or legal entity required by an order of a court to disclose AIDS confidential information in the custody or control of such person or legal entity shall disclose that information as required by that order.

(s) AIDS confidential information may be disclosed as medical information pursuant to Code Section 24-9-40, relating to the release of medical information, or pursuant to any other law which authorizes or requires the disclosure of medical information if:

(1) The person identified by that information:

(A) Has consented in writing to that disclosure; or

(B) Has been notified of the request for disclosure of that information at least ten days prior to the time the disclosure is to be made and does not object to such disclosure prior to the time specified for that disclosure in that notice; or

(2) A superior court in an in camera hearing finds by clear and convincing evidence a compelling need for the information which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the public health, safety, or welfare needs or any other public or private need for the disclosure against the privacy interest of the person identified by the information and the public interest which may be disserved by disclosures which may deter voluntary HIV tests. If the court determines that disclosure of that information is authorized under this paragraph, the court shall order that disclosure and impose appropriate safeguards against any unauthorized disclosure. The records of that hearing otherwise shall be under seal.

(t) (1) A superior court of this state may order a person or legal entity to disclose AIDS confidential information in its custody or control to:

(A) A prosecutor in connection with a prosecution for the alleged commission of reckless conduct under subsection (c) of Code Section 16-5-60;

(B) Any party in a civil cause of action; or



(C) A public safety agency or the Department of Human Resources if that agency or department has an employee thereof who has, in the course of that employment, come in contact with the body fluids of the person identified by the AIDS confidential information sought in such a manner reasonably likely to cause that employee to become an HIV infected person and provided the disclosure is necessary for the health and safety of that employee,

and for purposes of this subsection the term "petitioner for disclosure" means any person or legal entity specified in subparagraph (A), (B), or (C) of this paragraph.

(2) An order may be issued against a person or legal entity responsible for recording, reporting, or maintaining AIDS confidential information to compel the disclosure of that information if the petitioner for disclosure demonstrates by clear and convincing evidence a compelling need for the information which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the public health, safety, or welfare needs or any other public or private need for the disclosure against the privacy interest of the person identified by the information and the public interest which may be disserved by disclosures which may deter voluntary HIV tests.

(3) A petition seeking disclosure of AIDS confidential information under this subsection shall substitute a pseudonym for the true name of the person concerning whom the information is sought. The disclosure to the parties of that person's true name shall be communicated confidentially, in documents not filed with the court.

(4) Before granting any order under this subsection, the court shall provide the person concerning whom the information is sought with notice and a reasonable opportunity to participate in the proceedings if that person is not already a party.

(5) Court proceedings as to disclosure of AIDS confidential information under this subsection shall be conducted in camera unless the person concerning whom the information is sought agrees to a hearing in open court.

(6) Upon the issuance of an order that a person or legal entity be required to disclose AIDS confidential information regarding a person



named in that order, that person or entity so ordered shall disclose to the ordering court any such information which is in the control or custody of that person or entity and which relates to the person named in the order for the court to make an in camera inspection thereof. If the court determines from that inspection that the person named in the order is an HIV infected person, the court shall disclose to the petitioner for disclosure that determination and shall impose appropriate safeguards against unauthorized disclosure which shall specify the persons who may have access to the information, the purposes for which the information shall be used, and appropriate prohibitions on future disclosure.

(7) The record of the proceedings under this subsection shall be sealed by the court.

(8) An order may not be issued under this subsection against the Department of Human Resources, any county board of health, or any anonymous HIV test site operated by or on behalf of that department.

(u) A health care provider, health care facility, or other person or legal entity who, in violation of this Code section, unintentionally discloses AIDS confidential information, notwithstanding the maintenance of procedures thereby which are reasonably adopted to avoid risk of such disclosure, shall not be civilly or criminally liable, unless such disclosure was due to gross negligence or wanton and willful misconduct.

(v) AIDS confidential information may be disclosed when that disclosure is otherwise authorized or required by Code Section 42-1-6, if AIDS or HIV infection is the communicable disease at issue, or when that disclosure is otherwise authorized or required by any law which specifically refers to "AIDS confidential information," "HIV test results," or any similar language indicating a legislative intent to disclose information specifically relating to AIDS or HIV.

(w) A health care provider who has received AIDS confidential information regarding a patient from the patient's health care provider directly or indirectly under the provisions of subsection (i) of this Code section may disclose that information to a health care provider which has provided, is providing, or will provide any health care service to that patient and as a result of that provision of service that health care provider:

(1) Has personnel or patients who may be persons at risk of being infected with HIV by that patient, if that patient is an HIV infected person and such disclosure is reasonably necessary to protect any such personnel or patients from that risk; or



(2) Has a legitimate need for that information in order to provide that health care service to that patient.

(x) Neither the Department of Human Resources nor any county board of health shall disclose AIDS confidential information contained in its records unless such disclosure is authorized or required by this Code section or any other law, except that such information in those records shall not be a public record and shall not be subject to disclosure through subpoena, court order, or other judicial process.

(y) The protection against disclosure provided by Code Section 24-9-40.1 shall be waived and AIDS confidential information may be disclosed to the extent that the person identified by such information, his heirs, successors, assigns, or a beneficiary of such person, including but not limited to an executor, administrator, or personal representative of such person's estate:

(1) Files a claim or claims other entitlements under any insurance policy or benefit plan or is involved in any civil proceeding regarding such claim;

(2) Places such person's care and treatment, the nature and extent of his injuries, the extent of his damages, his medical condition, or the reasons for his death at issue in any civil or criminal proceeding; or

(3) Is involved in a dispute regarding coverage under any insurance policy or benefit plan.

(z) AIDS confidential information may be collected, used, and disclosed by an insurer in accordance with the provisions of Chapter 39 of Title 33, relating to the collection, use, and disclosure of information gathered by insurance institutions.

(aa) In connection with any civil or criminal action in which AIDS confidential information is disclosed as authorized or required by this Code section, the party to whom that information is thereby disclosed may subpoena any person to authenticate such AIDS confidential information, establish a chain of custody relating thereto, or otherwise testify regarding that information, including but not limited to testifying regarding any notifications to the patient regarding results of an HIV test. The provisions of this subsection shall apply as to records, personnel, or both of the Department of Human Resources or a county board of health notwithstanding Code Section 50-18-72, but only as to test results obtained by a prosecutor under subsection (q) of this Code section and to be used thereby in a prosecution for reckless conduct under subsection (c) of Code Section 16-5-60.

(bb) AIDS confidential information may be disclosed as a part of any proceeding or procedure authorized or required pursuant to Chapter 3, 4, or 7 of Title 37, regarding a person who is alleged to be or who is mentally ill, mentally



retarded, or alcoholic or drug dependent, or as a part of any proceeding or procedure authorized or required pursuant to Title 29, regarding the guardianship of a person or that person's estate, as follows:

(1) Any person who files or transmits a petition or other document which discloses AIDS confidential information in connection with any such proceeding or procedure shall provide a cover page which contains only the type of proceeding or procedure, the court in which the proceeding or procedure is or will be pending, and the words "CONFIDENTIAL INFORMATION" without in any way otherwise disclosing thereon the name of any individual or that such petition or other document specifically contains AIDS confidential information;

(2) AIDS confidential information shall only be disclosed pursuant to this subsection after disclosure to and with the written consent of the person identified by that information, or that person's parent or guardian if that person is a minor or has previously been adjudicated as being incompetent, or by order of court obtained in accordance with subparagraph (C) of paragraph (3) of this subsection;

(3) If any person files or transmits a petition or other document in connection with any such proceeding or procedure which discloses AIDS confidential information without obtaining consent as provided in paragraph (2) of this subsection, the court receiving such information shall either obtain written consent as set forth in that paragraph (2) for any further use or disclosure of such information or:

(A) Return such petition or other document to the person who filed or transmitted same, with directions against further filing or transmittal of such information in connection with such proceeding or procedure except in compliance with this subsection;

(B) Delete or expunge all references to such AIDS confidential information from the particular petition or other document; or

(C)

(i) If the court determines there is a compelling need for such information in connection with the particular proceeding or procedure, petition a superior court of competent jurisdiction for permission to obtain or disclose that information. If the person identified by the information is not yet represented by an attorney in the proceeding or procedure in connection with which the information is sought, the petitioning court shall appoint an



attorney for such person. The petitioning court shall have both that person and that person's attorney personally served with notice of the petition and time and place of the superior court hearing thereon. Such hearing shall not be held sooner than 72 hours after service, unless the information is to be used in connection with an emergency guardianship proceeding under Chapter 5 of Title 29, in which event the hearing shall not be held sooner than 48 hours after service.

(ii) The superior court in which a petition is filed pursuant to division (i) of this subparagraph shall hold an in camera hearing on such petition. The purpose of the hearing shall be to determine whether there is clear and convincing evidence of a compelling need for the AIDS confidential information sought in connection with the particular proceeding or procedure which cannot be accommodated by other means. In assessing compelling need, the superior court shall weigh the public health, safety, or welfare needs or any other public or private need for the disclosure against the privacy interest of the person identified by the information and the public interest which may be disserved by disclosures which may deter voluntary HIV tests. If the court determines that disclosure of that information is authorized under this subparagraph, the court shall order that disclosure and impose appropriate safeguards against any unauthorized disclosure. The records of that hearing otherwise shall be under seal; and

(4) The court having jurisdiction over such proceeding or procedure, when it becomes apparent that AIDS confidential information will likely be or has been disclosed in connection with such proceeding or procedure, shall take such measures as the court determines appropriate to preserve the confidentiality of the disclosed information to the maximum extent possible. Such measures shall include, without being limited to, closing the proceeding or procedure to the public and sealing all or any part of the records of the proceeding or procedure containing AIDS confidential information. The records of any appeals taken from any such proceeding or procedure shall also be sealed. Furthermore, the court may consult with and obtain the advice of medical experts or other counsel or



advisers as to the relevance and materiality of such information in such proceedings or procedures, so long as the identity of the person identified by such information is not thereby revealed.

EDITOR'S NOTES. --Ga. L. 1988, p. 1799, § 1, provides: "The General Assembly finds that Acquired Immunodeficiency Syndrome (AIDS) and its causative agent, including Human Immunodeficiency Virus (HIV), pose a grave threat to the health, safety, and welfare of the people of this state. In the absence of any effective vaccination or treatment for this disease, it threatens almost certain death to all who contract it. The disease is largely transmitted through sexual contacts and intravenous drug use, not through casual contact, and, while deadly, is therefore preventable. The key component of the fight against AIDS is education. Through public education and counseling our citizens can learn how the disease is transmitted and, thus, how to protect themselves and prevent its spread. The Department of Human Resources is encouraged to continue its efforts to educate all Georgians about the disease, its causative agent, and its means of transmission. In addition, voluntary testing should be encouraged for anyone who feels at risk of infection. While education, counseling, and voluntary testing are vital to the elimination of this epidemic, other measures are needed to protect the health of our citizens, and it is the intention of the General Assembly to enact such measures in the exercise of its police powers in order to deal with AIDS and HIV infection."



## APPENDIX "E"- New York Disclosure of AIDS Related Information Statute

Laws 1988, ch 584, § 1, eff Feb 1, 1989, provides as follows: Section 1. Legislative intent. The legislature recognizes that maximum confidentiality protection for information related to human immunodeficiency virus (HIV) infection and acquired immune deficiency syndrome (AIDS) is an essential public health measure. In order to retain the full trust and confidence of persons at risk, the state has an interest both in assuring that HIV related information is not improperly disclosed and in having clear and certain rules for the disclosure of such information. By providing additional protection of the confidentiality of HIV related information, the legislature intends to encourage the expansion of voluntary confidential testing for the human immunodeficiency virus (HIV) so that individuals may come forward, learn their health status, make decisions regarding the appropriate treatment, and change the behavior that puts them and others at risk of infection.

### PUBLIC HEALTH LAW

#### ARTICLE 27-F HIV and AIDS Related Information

NY CLS Pub Health § 2780 (1994)

#### § 2780. Definitions

As used in this article, the following terms shall have the following meanings:

1. "AIDS" means acquired immune deficiency syndrome, as may be defined from time to time by the centers for disease control of the United States public health service.
2. "HIV infection" means infection with the human immunodeficiency virus or any other related virus identified as a probable causative agent of AIDS.
3. "HIV related illness" means any illness that may result from or may be associated with HIV infection.
4. "HIV related test" means any laboratory test or series of tests for any virus, antibody, antigen or etiologic agent whatsoever thought to cause or to indicate the presence of AIDS.
5. "Capacity to consent" means an individual's ability, determined without regard to the individual's age, to understand and appreciate the nature and consequences of a proposed health care service, treatment, or procedure, or of a proposed disclosure of confidential HIV related information, as the case may be, and to make an informed decision concerning the service, treatment, procedure or disclosure.



6. "Protected individual" means a person who is the subject of an HIV related test or who has been diagnosed as having HIV infection, AIDS or HIV related illness.
7. "Confidential HIV related information" means any information, in the possession of a person who provides one or more health or social services or who obtains the information pursuant to a release of confidential HIV related information, concerning whether an individual has been the subject of an HIV related test, or has HIV infection, HIV related illness or AIDS, or information which identifies or reasonably could identify an individual as having one or more of such conditions, including information pertaining to such individual's contacts.
8. [Until Feb 1, 1993] "Health or social service" means any public or private care, treatment, clinical laboratory test, counseling or educational service for adults or children, and acute, chronic, custodial, residential, outpatient, home or other health care provided pursuant to this chapter or the social services law; public assistance or care as defined in article one of the social services law; employment-related services, housing services, foster care, shelter, protective services, day care, or preventive services provided pursuant to the social services law; services for the mentally disabled as defined in article one of the mental hygiene law; probation services, provided pursuant to articles twelve and twelve-A of the executive law; parole services, provided pursuant to article twelve-B of the executive law; correctional services, provided pursuant to the correction law; and detention and rehabilitative services provided pursuant to article nineteen-G of the executive law.
8. [Eff Feb 1, 1993] "Health or social service" means any public or private care, treatment, clinical laboratory test, counseling or educational service for adults or children, and acute, chronic, custodial, residential, outpatient, home or other health care provided pursuant to this chapter or the social services law; public assistance or care as defined in article one of the social services law; employment-related services, housing services, foster care, shelter, protective services, day care, or preventive services provided pursuant to the social services law; services for the mentally disabled as defined in article one of the mental hygiene law; probation services, provided pursuant to articles twelve and twelve-A of the executive law; parole services, provided pursuant to article twelve-B of the executive law; correctional services, provided pursuant to the correction law; detention and rehabilitative services provided pursuant to article nineteen-G of the executive law; and the activities of the health care worker HIV/HBV advisory panel pursuant to article twenty-seven-DD of this chapter.



9. "Release of confidential HIV related information" means a written authorization for disclosure of confidential HIV related information which is signed by the protected individual, or if the protected individual lacks capacity to consent, a person authorized pursuant to law to consent to health care for the individual. Such release shall be dated and shall specify to whom disclosure is authorized, the purpose for such disclosure and the time period during which the release is to be effective. A general authorization for the release of medical or other information shall not be construed as a release of confidential HIV related information, unless such authorization specifically indicates its dual purpose as a general authorization and an authorization for the release of confidential HIV related information and complies with the requirements of this subdivision.
10. "Contact" means an identified spouse or sex partner of the protected individual or a person identified as having shared hypodermic needles or syringes with the protected individual.
11. "Person" includes any natural person, partnership, association, joint venture, trust, public or private corporation, or state or local government agency.
12. "Health facility" means a hospital as defined in section two thousand eight hundred one of this chapter, blood bank, blood center, sperm bank, organ or tissue bank, clinical laboratory, or facility providing care or treatment to persons with a mental disability as defined in article one of the mental hygiene law.
13. "Health care provider" means any physician, nurse, provider of services for the mentally disabled as defined in article one of the mental hygiene law, or other person involved in providing medical, nursing, counseling, or other health care or mental health service, including those associated with, or under contract to, a health maintenance organization or medical services plan.
14. "Child" means any protected individual actually or apparently under eighteen years of age.
15. "Authorized agency" means any agency defined by section three hundred seventy-one of the social services law and, for the purposes of this article, shall include such corporations incorporated or organized under the laws of the state as may be specifically authorized by their certificates of incorporation to receive children for the purposes of adoption or foster care.
16. "Insurance institution" means any corporation, association, partnership, reciprocal exchange, interinsurer, fraternal benefits society, agent, broker or other entity including, but not limited to, any health maintenance



organization, medical service plan, or hospital plan which: (a) is engaged in the business of insurance; (b) provides health services coverage plans; or (c) provides benefits under, administers, or provides services for, an employee welfare benefit plan as defined in 29 U.S.C. 1002(1).

17. "Insurance support organization" means any person who regularly engages, in whole or in part, in the practice of assembling or collecting information about natural persons for the primary purpose of providing the information to an insurance institution for insurance transactions, including: (a) the furnishing of consumer reports or investigative consumer reports to an insurance institution [institution] \* for use in connection with an insurance transaction; or (b) the collection of personal information from insurance institutions or other insurance support organizations for the purpose of detecting or preventing fraud, material misrepresentation, or material non-disclosure in connection with insurance underwriting or insurance claim activity. The following persons shall not be considered "insurance-support organizations" for the purposes of this article: government institutions, insurance institutions, health facilities and health care providers.  
[\*Bracketed language inserted by the Publisher.]

#### § 2781. HIV related testing

1. Except as provided in section three thousand one hundred twenty-one of the civil practice law and rules, or unless otherwise specifically authorized or required by a state or federal law, no person shall order the performance of an HIV related test without first receiving the written, informed consent of the subject of the test who has capacity to consent or, when the subject lacks capacity to consent, of a person authorized pursuant to law to consent to health care for such individual. A physician or other person authorized pursuant to law to order the performance of an HIV related test shall certify, in the order for the performance of an HIV related test, that informed consent required by this section has been received prior to ordering such test by a laboratory or other facility.
2. Informed consent to an HIV related test shall consist of a statement signed by the subject of the test who has capacity to consent or, when the subject lacks capacity to consent, by a person authorized pursuant to law to consent to health care for the subject which includes at least the following:
  - (a) an explanation of the test, including its purpose, the meaning of its results, and the benefits of early diagnosis and medical intervention;  
and
  - (b) an explanation of the procedures to be followed, including that the test is voluntary, that consent may be withdrawn at any time, and a



statement advising the subject that anonymous testing is available;  
and

- (c) an explanation of the confidentiality protections afforded confidential HIV related information under this article, including the circumstances under which and classes of persons to whom disclosure of such information may be required, authorized or permitted under this article or in accordance with other provisions of law or regulation.

3. Prior to the execution of a written informed consent, a person ordering the performance of an HIV related test shall provide to the subject of an HIV related test or, if the subject lacks capacity to consent, to a person authorized pursuant to law to consent to health care for the subject, an explanation of the nature of AIDS and HIV related illness, information about discrimination problems that disclosure of the test result could cause and legal protections against such discrimination, and information about behavior known to pose risks for transmission and contraction of HIV infection.
4. A person authorized pursuant to law to order the performance of an HIV related test shall provide to the person seeking such test an opportunity to remain anonymous and to provide written, informed consent through use of a coded system with no linking of individual identity to the test request or results. A health care provider who is not authorized by the commissioner to provide HIV related tests on an anonymous basis shall refer a person who requests an anonymous test to a test site which does provide anonymous testing. The provisions of this subdivision shall not apply to a health care provider ordering the performance of an HIV related test on an individual proposed for insurance coverage.
5. At the time of communicating the test result to the subject of the test, a person ordering the performance of an HIV related test shall provide the subject of the test or, if the subject lacks capacity to consent, the person authorized pursuant to law to consent to health care for the subject with counseling or referrals for counseling: (a) for coping with the emotional consequences of learning the result; (b) regarding the discrimination problems that disclosure of the result could cause; (c) for behavior change to prevent transmission or contraction of HIV infection; (d) to inform such person of available medical treatments; and (e) regarding the test subject's need to notify his or her contacts.
6. The provisions of this section shall not apply to the performance of an HIV related test:



- (a) by a health care provider or health facility in relation to the procuring, processing, distributing or use of a human body or a human body part, including organs, tissues, eyes, bones, arteries, blood, semen, or other body fluids, for use in medical research or therapy, or for transplantation to individuals provided, however, that where the test results are communicated to the subject, post-test counseling, as described in subdivision five of this section, shall nonetheless be required; or
- (b) for the purpose of research if the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher; or
- (c) on a deceased person, when such test is conducted to determine the cause of death or for epidemiological purposes.

§ 2782. Confidentiality and disclosure

1. No person who obtains confidential HIV related information in the course of providing any health or social service or pursuant to a release of confidential HIV related information may disclose or be compelled to disclose such information, except to the following:
  - (a) the protected individual or, when the protected individual lacks capacity to consent, a person authorized pursuant to law to consent to health care for the individual;
  - (b) any person to whom disclosure is authorized pursuant to a release of confidential HIV related information;
  - (c) an agent or employee of a health facility or health care provider if (1) the agent or employee is permitted to access medical records, (2) the health facility or health care provider itself is authorized to obtain the HIV related information, and (3) the agent or employee provides health care to the protected individual, or maintains or processes medical records for billing or reimbursement;
  - (d) a health care provider or health facility when knowledge of the HIV related information is necessary to provide appropriate care or treatment to the protected individual or a child of the individual;
  - (e) a health facility or health care provider, in relation to the procurement, processing, distributing or use of a human body or a human body part, including organs, tissues, eyes, bones, arteries, blood, semen, or other body fluids, for use in medical education, research, therapy, or for transplantation to individuals;



- (f) health facility staff committees or accreditation or oversight review organizations authorized to access medical records; provided that such committees or organizations may only disclose confidential HIV related information: (1) back to the facility or provider of a health or social service; (2) to carry out the monitoring, evaluation, or service review for which it was obtained; or (3) to a federal, state or local government agency for the purposes of and subject to the conditions provided in subdivision six of this section;
- (g) a federal, state, county or local health officer when such disclosure is mandated by federal or state law;
- (h) an authorized agency in connection with foster care or adoption of a child. Such agency shall be authorized to redisclose such information only pursuant to this article or in accordance with the provisions of section three hundred seventy-three-a of the social services law;
- (i) third party reimbursers or their agents to the extent necessary to reimburse health care providers for health services; provided that, where necessary, an otherwise appropriate authorization for such disclosure has been secured by the provider;
- (j) an insurance institution, for other than the purpose set forth in paragraph (i) of this subdivision, provided the insurance institution secures a dated and written authorization that indicates that health care providers, health facilities, insurance institutions, and other persons are authorized to disclose information about the protected individual, the nature of the information to be disclosed, the purposes for which the information is to be disclosed and which is signed by:  
(1) the protected individual; (2) if the protected individual lacks the capacity to consent, such other person authorized pursuant to law to consent for such individual; or (3) if the protected individual is deceased, the beneficiary or claimant for benefits under an insurance policy, a health services plan, or an employee welfare benefit plan as defined in 29 U.S.C. 1002(1), covering such protected individual;
- (k) any person to whom disclosure is ordered by a court of competent jurisdiction pursuant to section twenty-seven hundred eighty-five of this article;
- (l) an employee or agent of the division of parole, in accordance with paragraph (a) of subdivision two of section twenty-seven hundred eighty-six of this article, to the extent the employee or agent is authorized to access records containing such information in order to carry out the division's functions, powers and duties with respect to



the protected individual, pursuant to section two hundred fifty-nine-a of the executive law;

- (m) an employee or agent of the division of probation and correctional alternatives or any local probation department, in accordance with paragraph (a) of subdivision two of section twenty-seven hundred eighty-six of this article, to the extent the employee or agent is authorized to access records containing such information in order to carry out the division's or department's functions, powers and duties with respect to the protected individual, pursuant to articles twelve and twelve-A of the executive law;
- (n) a medical director of a local correctional facility as defined in section forty of the correction law, in accordance with paragraph (a) of subdivision two of section twenty-seven hundred eighty-six of this article, to the extent the medical director is authorized to access records containing such information in order to carry out his or her functions, powers and duties with respect to the protected individual;  
or
- (o) an employee or agent of the commission of correction, in accordance with paragraph (a) of subdivision two of section twenty-seven hundred eighty-six of this article, to the extent the employee or agent is authorized to access records containing such information in order to carry out the commission's functions, powers and duties with respect to the protected individual, pursuant to article three of the correction law.
- (p) a law guardian, appointed to represent a minor pursuant to the social services law or the family court act, with respect to confidential HIV related information relating to the minor and for the purpose of representing the minor. If the minor has the capacity to consent, the law guardian may not redisclose confidential HIV related information without the minor's permission. If the minor lacks capacity to consent, the law guardian may redisclose confidential HIV related information for the sole purpose of representing the minor. This paragraph shall not limit a law guardian's ability to seek relief under section twenty-seven hundred eighty-five of this chapter.

2. A state, county or local health officer may disclose confidential HIV related information when:

- (a) disclosure is specifically authorized or required by federal or state law;  
or



- (b) disclosure is made pursuant to a release of confidential HIV related information; or
- (c) disclosure is requested by a physician pursuant to subdivision four of this section; or
- (d) disclosure is authorized by court order pursuant to the provisions of section twenty-seven hundred eighty-five of this article.

3. No person to whom confidential HIV related information has been disclosed pursuant to this article shall disclose the information to another person except as authorized by this article, provided, however, that the provisions of this subdivision shall not apply:

- (a) to the protected individual; or
- (b) to a natural person who is authorized pursuant to law to consent to health care for the protected individual; or
- (c) to a protected individual's foster parent as defined in section three hundred seventy-one of the social services law and subject to regulations promulgated pursuant to paragraph (a) of subdivision two of section twenty-seven hundred eighty-six of this article, for the purpose of providing care, treatment or supervision of the protected individual; or
- (d) a prospective adoptive parent as specified in section three hundred seventy-three-a of the social services law and subject to regulations promulgated pursuant to paragraph (a) of subdivision two of section twenty-seven hundred eighty-six of this article with whom a child has been placed for adoption.

4. (a) A physician may disclose confidential HIV related information under the following conditions:

- (1) disclosure is made to a contact or to a public health officer for the purpose of making the disclosure to said contact; and
- (2) the physician reasonably believes disclosure is medically appropriate and there is a significant risk of infection to the contact; and
- (3) the physician has counseled the protected individual regarding the need to notify the contact, and the



physician reasonably believes the protected individual will not inform the contact; and

- (4) the physician has informed the protected individual of his or her intent to make such disclosure to a contact and has given the protected individual the opportunity to express a preference as to whether disclosure should be made by the physician directly or to a public health officer for the purpose of said disclosure. If the protected individual expresses a preference for disclosure by a public health officer or by the physician, the physician shall honor such preference.
- (b) When making such disclosures to the contact, the physician or public health officer shall provide or make referrals for the provision of the appropriate medical advice and counseling for coping with the emotional consequences of learning the information and for changing behavior to prevent transmission or contraction of HIV infection. The physician or public health officer shall not disclose the identity of the protected individual or the identity of any other contact. A physician or public health officer making a notification pursuant to this subdivision shall make such disclosure in person, except where circumstances reasonably prevent doing so.
- (c) A physician or public health officer shall have no obligation to identify or locate any contact.
- (d) A physician may, upon the consent of a parent or guardian, disclose confidential HIV related information to a state, county, or local health officer for the purpose of reviewing the medical history of a child to determine the fitness of the child to attend school.
- (e) A physician may disclose confidential HIV related information pertaining to a protected individual to a person (known to the physician) authorized pursuant to law to consent to health care for a protected individual when the physician reasonably believes that: (1) disclosure is medically necessary in order to provide timely care and treatment for the protected individual; and (2) after appropriate counseling as to the need for such disclosure, the protected individual will not inform a person authorized by law to consent to health care; provided, however, that the physician shall not make such disclosure if, in the judgment of the physician: (A) the disclosure would not be in the best interest of the protected individual; or (B) the protected individual is authorized pursuant to



law to consent to such care and treatment. Any decision or action by a physician under this paragraph, and the basis therefor, shall be recorded in the protected individual's medical record.

5. (a) Whenever disclosure of confidential HIV related information is made pursuant to this article, except for disclosures made pursuant to paragraph (a) of subdivision one of this section or paragraph (a) or (e) of subdivision four of this section, such disclosure shall be accompanied or followed by a statement in writing which includes the following or substantially similar language: "This information has been disclosed to you from confidential records which are protected by state law. State law prohibits you from making any further disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. Any unauthorized further disclosure in violation of state law may result in a fine or jail sentence or both. A general authorization for the release of medical or other information is NOT sufficient authorization for further disclosure." An oral disclosure shall be accompanied or followed by such a notice within ten days.
- (b) Except for disclosures made pursuant to paragraph (c) of subdivision one of this section, or to persons reviewing information or records in the ordinary course of ensuring that a health facility is in compliance with applicable quality of care standards or any other authorized program evaluation, program monitoring or service review, or to governmental agents requiring information necessary for payments to be made on behalf of patients or clients pursuant to contract or in accordance to law, a notation of all such disclosures shall be placed in the medical record of a protected individual, who shall be informed of such disclosures upon request; provided, however, that for disclosures made to insurance institutions such a notation need only be entered at the time the disclosure is first made.
6. (a) The provisions of this subdivision shall apply where a provider of a health or social service possesses confidential HIV related information relating to individuals who are recipients of the service, and a federal, state or local government agency supervises or monitors the provider or administers the program under which the service is provided.
- (b) Confidential HIV related information relating to a recipient of such service may be disclosed in accordance with regulations promulgated pursuant to paragraph (a) of subdivision two of section twenty-seven hundred eighty-six of this article to an authorized employee or agent of such provider or government agency, when reasonably necessary



for such supervision, monitoring, administration, or provision of such service. The term "authorized employee or agent", as used in this subdivision shall only include any employee or agent who would, in the ordinary course of business of the provider or government agency, have access to records relating to the care of, treatment of, or provision of a health or social service to the protected individual.

7. Nothing in this section shall limit a person's or agency's responsibility or authority to report, investigate, or redisclose, child protective and adult protective services information in accordance with title six of article six and titles one and two of article nine-B of the social services law, or to provide or monitor the provision of child and adult protective or preventive services.
8. Confidential HIV related information shall be recorded in the medical record of the protected individual. The provisions of this section shall not prohibit the listing of acquired immune deficiency syndrome, HIV related illness or HIV infection in a certificate of death, autopsy report or related documents prepared pursuant to article forty-one of this chapter or other applicable laws, ordinances, rules or regulations relating to the documentation of cause of death, nor shall this section be construed to modify any laws, ordinances, rules or regulations relative to access to death certificates, autopsy reports or such other related documents. Under no circumstances shall confidential HIV related information be disclosable pursuant to article six of the public officers law.
9. Confidential HIV related information shall be disclosed upon the request of the health care worker HIV/HBV advisory panel, established pursuant to article twenty-seven-DD of this chapter, to the panel or its designee only when reasonably necessary for the evaluation of a worker who has voluntarily sought the panel's review.

#### § 2783. Penalties; immunities

##### 1. Any person who shall:

- (a) perform, or permit or procure the performance of, an HIV related test in violation of section twenty-seven hundred eighty-one of this article; or
- (b) disclose, or compel another person to disclose, or procure the disclosure of, confidential HIV related information in violation of section twenty-seven hundred eighty-two of this article; shall be subject to a civil penalty not to exceed five thousand dollars for each



occurrence. Such penalty may be recovered in the same manner as the penalty provided in section twelve of this chapter.

2. Any person who willfully commits an act enumerated in subdivision one of this section shall be guilty of a misdemeanor and subject to the penalties provided in section twelve-b of this chapter.
3. There shall be no criminal sanction or civil liability on the part of, and no cause of action for damages shall arise against any physician or his or her employer, or health facility or health care provider with which the physician is associated, or public health officer, solely on account of:
  - (a) the failure to disclose confidential HIV related information to a contact or person authorized pursuant to law to consent to health care for a protected individual; or
  - (b) disclosure of confidential HIV related information to a contact or person authorized pursuant to law to consent to health care for a protected individual, when carried out in good faith and without malice, and in compliance with this article; or
  - (c) the disclosure of confidential HIV related information to any person, agency, or officer authorized to receive such information, when carried out in good faith and without malice, and in compliance with the provisions of this article.
4. Any cause of action to recover damages based on a failure to provide information, explanations, or counseling prior to the execution of a written informed consent, or based on a lack of informed consent in the ordering or performance of an HIV related test in violation of this article shall be governed by the provisions of section two thousand eight hundred five-d of this chapter.

§ 2784. Applicability to insurance institutions and insurance support organizations

Except for disclosure to third party reimbursers and insurance institutions pursuant to paragraphs (i) and (j) of subdivision one of section twenty-seven hundred eighty-two of this article and except for disclosures pursuant to section twenty-seven hundred eighty-five of this article, the provisions of this article shall not apply to insurance institutions and insurance support organizations, except that health care providers associated with or under contract to a health maintenance organization or other medical services plan shall be subject to the provisions of this article.

§ 2785. Court authorization for disclosure of confidential HIV related information



1. Notwithstanding any other provision of law, no court shall issue an order for the disclosure of confidential HIV related information, except a court of record of competent jurisdiction in accordance with the provisions of this section.
2. A court may grant an order for disclosure of confidential HIV related information upon an application showing: (a) a compelling need for disclosure of the information for the adjudication of a criminal or civil proceeding; (b) a clear and imminent danger to an individual whose life or health may unknowingly be at significant risk as a result of contact with the individual to whom the information pertains; (c) upon application of a state, county or local health officer, a clear and imminent danger to the public health; or (d) that the applicant is lawfully entitled to the disclosure and the disclosure is consistent with the provisions of this article.
3. Upon receiving an application for an order authorizing disclosure pursuant to this section, the court shall enter an order directing that all pleadings, papers, affidavits, judgments, orders of the court, briefs and memoranda of law which are part of the application or the decision thereon, be sealed and not made available to any person, except to the extent necessary to conduct any proceedings in connection with the determination of whether to grant or deny the application, including any appeal. Such an order shall further direct that all subsequent proceedings in connection with the application shall be conducted in camera, and, where appropriate to prevent the unauthorized disclosure of confidential HIV related information, that any pleadings, papers, affidavits, judgments, orders of the court, briefs and memoranda of law which are part of the application or the decision thereon not state the name of the individual concerning whom confidential HIV related information is sought.
4. (a) The individual concerning whom confidential HIV related information is sought and any person holding records concerning confidential HIV related information from whom disclosure is sought shall be given adequate notice of such application in a manner which will not disclose to any other person the identity of the individual, and shall be afforded an opportunity to file a written response to the application, or to appear in person for the limited purpose of providing evidence on the statutory criteria for the issuance of an order pursuant to this section.  
  
(b) The court may grant an order without such notice and opportunity to be heard, where an ex parte application by a public health officer shows that a clear and imminent danger to an individual whose life or health may unknowingly be at risk requires an immediate order.



(c) Service of a subpoena shall not be subject to this subdivision.

5. In assessing compelling need and clear and imminent danger, the court shall provide written findings of fact, including scientific or medical findings, citing specific evidence in the record which supports each finding, and shall weigh the need for disclosure against the privacy interest of the protected individual and the public interest which may be disserved by disclosure which deters future testing or treatment or which may lead to discrimination.

6. An order authorizing disclosure of confidential HIV related information shall:

- (a) limit disclosure to that information which is necessary to fulfill the purpose for which the order is granted; and
- (b) limit disclosure to those persons whose need for the information is the basis for the order, and specifically prohibit redisclosure by such persons to any other persons, whether or not they are parties to the action; and
- (c) to the extent possible consistent with this section, conform to the provisions of this article; and
- (d) include such other measures as the court deems necessary to limit any disclosures not authorized by its order.

§ 2786. Rules and regulations; forms; report

1. The commissioner shall promulgate rules and regulations concerning implementation of this article for health facilities, health care providers and other persons to whom this article is applicable. The commissioner shall also develop forms to be used for informed consent for HIV related testing and for the release of confidential HIV related information and materials for pre-test counseling as required by subdivision three of section twenty-seven hundred eighty-one of this article, and for post-test counseling as required by subdivision five of section twenty-seven hundred eighty-one of this article. Persons, health facilities and health care providers may use forms for informed consent for HIV related testing, and for the release of confidential HIV related information other than those forms developed pursuant to this section, provided that the person, health facility or health care provider doing so receives prior authorization from the commissioner. All forms developed or authorized pursuant to this section shall be written in a clear and coherent manner using words with common, everyday meanings. The commissioner, in consultation with the AIDS institute advisory council, shall promulgate regulations to identify those circumstances which create a significant risk of contracting or transmitting



HIV infection; provided, however, that such regulations shall not be determinative of any significant risk determined pursuant to paragraph (a) of subdivision four of section twenty-seven hundred eighty-two or section twenty-seven hundred eighty-five of this article.

2. (a) Each state agency authorized pursuant to this article to obtain confidential HIV related information shall, in consultation with the department of health, promulgate regulations: (1) to provide safeguards [safeguards] \* to prevent discrimination, abuse or other adverse actions directed toward protected individuals; (2) to prohibit the disclosure of such information except in accordance with this article; (3) to seek to protect individuals in contact with the protected individual when such contact creates a significant risk of contracting or transmitting HIV infection through the exchange of body fluids, and (4) to establish criteria for determining when it is reasonably necessary for a provider of a health or social service or the state agency or a local government agency to have or to use confidential HIV related information for supervision, monitoring, investigation, or administration and for determining which employees and agents may, in the ordinary course of business of the agency or provider, be authorized to access confidential HIV related information pursuant to the provisions of paragraphs (l) and (m) of subdivision one and subdivision six of section twenty-seven hundred eighty-two of this article; and provided further that such regulations shall be promulgated by the chairperson of the commission of correction where disclosure is made pursuant to paragraphs (n) and (o) of subdivision one of section twenty-seven hundred eighty-two of this article. [\*Bracketed language inserted by the Publisher.]
- (b) The department of health, in consultation with agencies referred to in paragraph (a) of this subdivision, shall submit a report to the legislature by December first, nineteen hundred eighty-nine, outlining the status and content of such regulations, their effect on the regulated facilities and the protected individuals served by them, the extent to which they conform with current medical and scientific knowledge on the transmissibility of HIV infection, and any recommendations for changes in said regulations.

#### § 2787. Separability

If any section, clause or provision of this article shall be deemed by any court of competent jurisdiction to be unconstitutional or ineffective in whole or in part, to the extent that it is not unconstitutional or ineffective, it shall be valid and effective and no other section, clause or provision shall on account thereof be deemed invalid or ineffective.



APPENDIX "F" - Georgia Criminal AIDS Transmission Statute

TITLE 16. CRIMES AND OFFENSES  
CHAPTER 5. CRIMES AGAINST THE PERSON  
ARTICLE 4. RECKLESS CONDUCT

O.C.G.A. § 16-5-60 (1994)

§ 16-5-60. Reckless conduct causing harm to or endangering the bodily safety of another;  
conduct by HIV infected persons

(a) Any term used in this Code section and defined in Code Section 31-22-9.1 shall have the meaning provided for such term in Code Section 31-22-9.1.

(b) A person who causes bodily harm to or endangers the bodily safety of another person by consciously disregarding a substantial and unjustifiable risk that his act or omission will cause harm or endanger the safety of the other person and the disregard constitutes a gross deviation from the standard of care which a reasonable person would exercise in the situation is guilty of a misdemeanor.

(c) A person who is an HIV infected person who, after obtaining knowledge of being infected with HIV:

(1) Knowingly engages in sexual intercourse or performs or submits to any sexual act involving the sex organs of one person and the mouth or anus of another person and the HIV infected person does not disclose to the other person the fact of that infected person's being an HIV infected person prior to that intercourse or sexual act;

(2) Knowingly allows another person to use a hypodermic needle, syringe, or both for the introduction of drugs or any other substance into or for the withdrawal of body fluids from the other person's body and the needle or syringe so used had been previously used by the HIV infected person for the introduction of drugs or any other substance into or for the withdrawal of body fluids from the HIV infected person's body and where that infected person does not disclose to the other person the fact of that infected person's being an HIV infected person prior to such use;



(3) Offers or consents to perform with another person an act of sexual intercourse for money without disclosing to that other person the fact of that infected person's being an HIV infected person prior to offering or consenting to perform that act of sexual intercourse;

(4) Solicits another person to perform or submit to an act of sodomy for money without disclosing to that other person the fact of that infected person's being an HIV infected person prior to soliciting that act of sodomy;  
or

(5) Donates blood, blood products, other body fluids, or any body organ or body part without previously disclosing the fact of that infected person's being an HIV infected person to the person drawing the blood or blood products or the person or entity collecting or storing the other body fluids, body organ, or body part,

is guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not more than ten years.







# FINANCIAL ASSISTANCE FOR BLOOD-RELATED INJURIES

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# **FINANCIAL ASSISTANCE FOR BLOOD-RELATED INJURIES**

## **INTRODUCTION**

The analysis of compensation mechanisms involves wider aspects of social policy, moral philosophy and economic theory. Historically, the method of compensation utilized in our legal system has been fault based. This stems from the premise that events which take place between two autonomous people are matters of their own concern. However, community based theories have proposed that many private wrongs are also a matter of public concern.

This community aspect is not unique within the legal system. The criminal law, for example, views harms which occur to an individual as affecting the community at large. A wrongdoer in the criminal context is characterized as a threat to society in general. Many jurisdictions provide special compensation rules for the “innocent” victims of crime. Society at large takes some responsibility for the risk of such an occurrence by compensating for the result. In short, the individual’s loss is spread to the community at large.

One rationale for such societal acceptance of responsibility is that the risk imposed on the individual is to a great degree a function of societal decisions in resource allocation. Society could choose to substantially reduce the risk of violent crime by, for example, having sufficient police to patrol each block of the city. It chooses to use its resources otherwise and thereby increases the risk to the individual. Hence it is seen as “fair” for society to subsidize the individual on whom the risk operated.

If one accepts that the blood supply, essentially publicly funded and regulated, will continue to contain risks to individuals which, although statistically low in occurrence, can and will have severe economic consequences at the individual level, it is difficult to rationalize a refusal by society to subsidize the injured individual for accepting such public risks.

This is especially the case where the “product” is not one subject to the usual market economy factors but is an integral part of the provision of medical treatment and services.



The efficacy of the current schemes of compensation under traditional tort is debatable because:

- (a) it concentrates on the conduct of the defendant, while ignoring the plight of the injured;
- (b) the litigation process is slow moving, expensive and involves considerable risk of failure; and
- (c) it is based on fictions which are especially apparent with respect to blood and blood product issues. These fictions include: that a responsible party should be identified to compensate the victim for loss; that it educates the public and the supplier by illustrating what are reasonable and unreasonable standards of conduct; and that adverse judgments will drive those suppliers who create risks from the marketplace.

### **THE DEFICITS OF THE CURRENT SYSTEM**

It is debatable whether current Canadian tort principles provide a valid, rational compensation mechanism and a balance of public and private interests in the context of blood and blood product related injury. The call for an alternate compensation scheme for blood and blood product related injuries has usually been approached from two perspectives:

- (a) the inability of the tort system to compensate where the injury was not caused by demonstrative fault;
- (b) the efficacy of the tort system as a means of determining “fault” and deterring those who create risks from continuing unreasonable standards of conduct.



(a) Individuals Bear the Unavoidable Risks

Ison, in *The Forensic Lottery*, comments:

The principle upon which the system is generally assumed to rest is that he who by his negligence causes injury or damage to another should pay for the harm so caused. The main objection to the principle is that compensation for the accident victim is made to depend not simply on his losses, his need, or the merits of his conduct, but on the largely fortuitous circumstance of whether he can blame anyone. Conversely, the condemnation of the defendant is made to depend not so much on the culpability of his conduct as on its largely fortuitous consequence.<sup>1</sup>

Ison poses the question: “if the knife slips in an operation and the patient is disabled, does it really make any sense that the financial destiny of the patient and his family should depend upon an esoteric inquiry into whether the knife slipped through carelessness and despite the use of reasonable care?”

Ison further asserts that liability for negligence is a capricious and unsatisfactory method of compensating the victims of injury or disease. He states that it is thoroughly inefficient as a method of social cost accounting, and its influence on rehabilitation is harmful in far more cases than it is beneficial. He asserts that such liability principles do not form a comprehensive or rational system of income security or loss compensation but that in fact the distribution of losses and the financial destiny of the victim depend upon a series of chance factors interacting to produce results in each case that depend very largely on sheer luck. He concludes that the overall cost of administering the system is so high that the burdens of liability are roughly double the benefits of compensation.

Academics and judiciary alike have severely criticized the current model (tort liability) for its inability to compensate in the absence of “fault”. The Prichard Report in 1990 referenced many of these criticisms including those of Mr. Justice Krever:

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<sup>1</sup> Staples Press, London, p. 7



I confess to a feeling of discomfort over a state of affairs, in an enlightened and compassionate society, in which a patient, who undergoes a necessary procedure and who cannot afford to bear the entire loss, through no fault of his and reposing full confidence in our system of medical care, suffers catastrophic disability but is not entitled to be compensated because of the absence of fault on the part of those involved in his care. While it may be that there is no remedy for this unfortunate and brave plaintiff and that this shortcoming should not be corrected judicially, there is, in my view, an urgent need for correction.<sup>2</sup>

(b) Tort Liability as a Deterrence Factor

In criticizing tort liability as a deterrence factor, Ison states:

1. Tort liability creates an incentive to minimize the risk of liability which is not the same thing as an incentive to prevent injury.
2. Tort liability does not require any particular response and consequently may result in over deterrence.
3. The court cannot order or supervise a program of improvement.
4. Relying on tort liability as the deterrence force may detract from the use of direct regulation or satisfactory levels of surveillance.
5. Tort liability may impede rather than advance the making of rational decisions as to what levels of risk are acceptable.
6. Tort liability can damage in retrospect and fails to prescribe an advance about any particular level of acceptable risk.<sup>3</sup>

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<sup>2</sup> *Ferguson v. Hamilton Civic Hospital* (1983), 23 C.C.L.T. 254 at 313

<sup>3</sup> *Ibid.*, p. 46



Fear of liability may overdeter to the detriment of the public interest. As a recent and real example, a voluntary standard-setting organization seriously considered ceasing that function in the wake of a court decision holding it negligent.<sup>4</sup>

It should be noted that other compensation mechanisms such as automobile no-fault schemes, workers' compensation laws, and compensation for the victims of crime operate successfully independent from traditional tort regime.<sup>5</sup>

### ALTERNATE MODELS FOR FINANCIAL ASSISTANCE

In the context of blood and blood supply many models have been proposed for alternate compensation mechanisms.

Garza<sup>6</sup> proposes a system modeled after the National Vaccine Injury Compensation Program. O'Connell<sup>7</sup> suggested an industry driven settlement system. Robertson<sup>8</sup> suggested a no-fault system with reservations as to how one would determine a medical event versus a pre-existing condition. Elgin<sup>9</sup> notes that in the medical field less than 10% of viable claims result in compensation.

The Prichard Report extensively examined the costs of the current system and suggested

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<sup>4</sup> *Snyder v. AABB*, (1995) 665 A 2d 1107 prompted the American Association of Blood Banks to consider whether it wanted to limit or abandon its role as a standard-setting organization. After much deliberation, it decided to reaffirm its commitment to that function.

<sup>5</sup> See Dewees and Trebilcock, *The Efficacy of the Tort System* (1992) Osgoode Hall Law Review 56; and Coast et al *Medical Practice in Canada* (1991), 324 N.E.J.M. 89

<sup>6</sup> (1993) *Administrative No Fault Recovery for Transfusions - HIV*

<sup>7</sup> (1996) *Neo No-Fault Remedies*

<sup>8</sup> (1990) *Contemporary Law: Reform of the Law of Medical Liability* 172

<sup>9</sup> (1993) *Health Law Journal* 96



a series of procedure changes to modify the current system and also suggested overall compensation reform whereby there would be the development of a no-fault compensation scheme for persons suffering significant avoidable health care injuries. An avoidable injury was defined as one which, with the benefit of hindsight could have been avoided by the use of alternate techniques. The scheme envisioned would be an alternative to the tort system, requiring an election on the part of the injured patient and a system which would be sufficiently broad to encompass vaccine, blood product and pharmaceutical injuries. However, a continued focus on the avoidability of injury merely perpetuates the "forensic lottery" described above.



## CONCLUSION AND RECOMMENDATIONS

Despite best efforts of modern science and technology, the blood supply will continue to expose individuals to risk of severe injury and consequent financial loss. In addition, the overall safety of the blood supply involves weighing risks and benefits, which may require some risks to be tolerated on a system basis to avoid other risks to safety or security.

It is not reasonable for a few individuals to shoulder the burden of those risks - society's risks - alone. The traditional tort system has proven to be an unsatisfactory and inefficient method of relieving hardship for those few individuals who bear the risk for us all. Furthermore, the tort system can only provide relief if it can be proven that the risk was avoidable, even though the individuals suffer whether the cause was avoidable or not.

For all the above reasons, the Red Cross recommends the following:

- **That the governments be urged to provide special financial assistance for those infected with hepatitis C through blood or blood products.**

The Canadian Red Cross understands the many complex factors that ministers must take into account in dealing with this type of issue. But it believes, however, that the ministers' recent decision not to consider providing such assistance should be reviewed. Given the crisis of confidence in Canada's blood supply, it is particularly important that the blood system stop being pilloried in an ongoing public battle for assistance to those who--through no fault of their own--have been infected by blood and blood products. It should not be necessary for such people to have to prove negligence to receive an appropriate level of assistance to deal with their illness.

The Canadian Red Cross has stated repeatedly that it supports any responsible initiative on the part of the blood system's funders and other stakeholders to set up a financial assistance



program for the benefit of individuals infected with hepatitis C where that infection can be clearly linked to blood products. The time has come for governments to take this initiative.

- **That for the future, a national system be established to administer a program of financial assistance for those who can establish that they have suffered injury from the use of blood or blood products in Canada. Relief should be based on their need, not on whether their loss was avoidable. The traditional tort system should remain an option for those individuals who elect not to participate in the administrative system.**

The provincial, territorial and federal governments must take a leadership role in establishing such a system, as it is an issue of public interest. However, private corporations and other bodies and groups such as fractionators, hospitals, and physicians, would be expected to participate in the system and thus should be consulted on its design, development, and implementation.

The Canadian Red Cross Society

December 6, 1996













